

NATIONAL QUALITY FORUM

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NEUROLOGY ENDORSEMENT MAINTENANCE

STEERING COMMITTEE

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THURSDAY

JUNE 21, 2012

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The Steering Committee met at the National Quality Forum, 9th Floor Conference Room, 1030 15th Street, NW., Washington, D.C., at 8:00 a.m., David Knowlton and David Tirschwell, Co-Chairs, presiding.

PRESENT:

DAVID KNOWLTON, M.A., Co-Chair, New Jersey Health Care Quality Institute

DAVID TIRSCHWELL, M.D., M.Sc., Co-Chair, University of Washington

A.M. BARRETT, M.D., Stroke Rehabilitation Research, Kessler Foundation

WILLIAM BARSAN, M.D., University of Michigan Health System

JOCELYN BAUTISTA, M.D., MBA, Cleveland Clinic

RAMON BAUTISTA, M.D., MBA, University of Florida HSC/Jacksonville

GWENDOLEN BUHR, M.D., Duke University

GAIL AUSTIN COONEY, M.D., FAAHPM, Hospice of Palm Beach County/Spectrum Health Inc.

JORDAN EISENSTOCK, M.D., CPE, UMass Memorial Medical Center

RISHA GIDWANI, Dr.PH., Stanford University Medical Center

DAVID HACKNEY, M.D., Beth Israel Deaconess

Medical Center

GREGORY KAPINOS, M.D., MS, North Shore-LIJ Health System

PRESENT(Cont'd):

MICHAEL KAPLITT, M.D., Ph.D., Weill Cornell
Medical College

DANIEL LABOVITZ, Montefiore Medical Center

THERESE RICHMOND, Ph.D., CRNP, FAAN,
University of Pennsylvania, School of
Medicine

JACK SCARIANO, M.D., PLLC, Neurologist, Fort
Sanders Parkwest Medical Center and
Tennova West Medical Center

RAJ SHETH, M.D., Nemours Children's Clinic

JOLYNN SUKO, MPH, Virginia Mason Medical
Center

JANE SULLIVAN, PT, DHS, MS, Northwestern
University Feinberg School of Medicine

FREDRIK TOLIN, M.D., MBA, FACS, Humana

MARY VAN de KAMP, CCC-SLP, RehabCare,
Kindred Healthcare

SALINA WADDY, M.D., National Institutes of
Health

NQF STAFF:

HELEN BURSTIN, M.D., Senior Vice President,
Performance Measures

ANN HAMMERSMITH, J.D., General Counsel

KAREN JOHNSON, MS, Senior Director,
Performance Measures

KAREN PACE, RN, Ph.D., Senior Director,
Performance Measures

SUZANNE THEBERGE, MPH, Project Manager,
Performance Measures

JESSICA WEBER, MPH, Project Analyst,
Performance Measures

ALSO PRESENT:

MARK ANTMAN, DDS, MBA, American Medical Association

SUSANNAH BERNHEIM, M.D., Yale New Haven Health System Center for Outcomes Research and Evaluation

JOHN BOTT, Agency for Healthcare Research and Quality*

ELIZABETH DRYE, M.D., SM, Yale New Haven Health System Center for Outcomes Research and Evaluation

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IRENE KATZAN, M.D., MS, Cleveland Clinic

KAREN KOLBUSZ, The Joint Commission

HARLAN KRUMHOLZ, M.D., Yale New Haven Health System Center for Outcomes Research and Evaluation*

JUDITH LICHTMAN, Yale New Haven Health System Center for Outcomes Research and

Evaluation

ROB MULLEN, Ph.D., American Speech-Language-Hearing Association*

PATRICK ROMANO, University of California Davis Medical Group

SARAH TONN, MPH, American Academy of Neurology

ANN WATT, MBA, The Joint Commission

LAURA YODICE, MPH, MHA, American Medical Association

PAT ZRELAK, Ph.D., RN, University of California Davis Center for Healthcare Policy and Research *

*present by teleconference

CONTENTS

Welcome, Recap of Day 1	6
NQF Perspective on Risk Adjustment	7
Consideration of Candidate Measures	
0467: Acute Stroke Mortality Rate	22
2026: Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following an Acute Ischemic Stroke Hospitalization	84
2027: Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following an Acute Ischemic Stroke Hospitalization	122
0446: Functional Communication Measure: Reading	192
0442: Functional Communication Measure: Writing	234
0443: Functional Communication Measure: Swallowing	
0444: Functional Communication Measure: Spoken Language Expression	
0445: Functional Communication Measure: Spoken Language Comprehension	
0447: Functional Communication Measure: Motor Speech	
0448: Functional Communication Measure: Memory	
0449: Functional Communication Measure: Attention	
NQF Member and Public Comment	260
Additional Discussion Topics	
Related and Competing Measures	264
Measure Harmonization	273
Measure Gaps	364
NQF Member and Public Comment	394
Next Steps and Committee Timeline	395

1 P-R-O-C-E-E-D-I-N-G-S

2 8:06 a.m.

3 MS. JOHNSON: Okay, good morning
4 everyone. Thank you again for participating
5 in our meeting. I know that we had a really
6 great meeting yesterday, we got a lot
7 accomplished.

8 So what we're going to do this
9 morning, first thing we're going to change the
10 agenda just a little bit. We're going to hand
11 it over for a couple of minutes to David and
12 Dave who are going to give us a quick recap of
13 what happened yesterday.

14 And then we're going to hear from
15 Karen Pace. Karen is another senior director
16 here at NQF in the performance measures
17 department and she is also our chief
18 methodologist. And she is going to give us
19 some background information just to help us
20 think through some of the issues related to
21 risk adjustment. So it will be a nice
22 overview before we delve deep into the

1 mortality and readmission measures.

2 So with that I'm going to hand it
3 over to our co-chairs.

4 CO-CHAIR TIRSCHWELL: Good
5 morning, everyone. Welcome back.

6 So, the summary can be really
7 quick. We reviewed I'm told 18 measures
8 yesterday and 5 of them did not meet criteria
9 for approval. Suzanne, can you tell us what
10 those five were off the top of your head?

11 MS. THEBERGE: Yes, I can. It was
12 the 0242 t-PA Considered, 2022 t-PA Initiated,
13 2017 CT or MRI Reports, and 0440 Stroke
14 Education and 1955 NIH Stroke Scale Reporting.

15 CO-CHAIR TIRSCHWELL: Thank you.
16 And today obviously we have a bunch more
17 measures. It's a little bit different focus.
18 A lot of these are outcome measures today as
19 opposed to process yesterday. We're going to
20 hear a little bit about methods which I think
21 are inherently a lot more complicated today
22 than they were yesterday.

1 And the schedule's been modified
2 just a little bit. I'm not sure, when are we
3 going to do the competing? At the end of the
4 day. Okay, very good. Thank you.

5 DR. PACE: Good morning, everyone.
6 I'm glad to be here. And we thought it would
7 be good because the day is primarily devoted
8 to outcome measures to give a little
9 background and NQF perspective on risk
10 adjustment.

11 These are, as has already been
12 stated, more complex than the process measures
13 that you've been looking at. It's -- we
14 appreciate the questions and issues that
15 people have been raising because it means
16 you're taking a close look at the measures and
17 identifying things and trying to understand
18 what's going on. So we just want to give you
19 a little background. And Jessica, you want to
20 move to the next slide?

21 So, just to give you a quick
22 background we've endorsed measures with a

1 variety of risk adjustment approaches. So,
2 you're going to see three different approaches
3 today in the measures you're looking at and
4 there are more than that. And just to -- so
5 the other thing from that is that the NQF
6 criteria address risk adjustment, and I'll go
7 into more detail about that, but do not
8 dictate a specific statistical approach.

9 We don't require and we currently
10 don't have a mechanism for head-to-head
11 comparisons of different statistical risk
12 adjustment approaches to the same data set.
13 So it is complex, it's hard for, you know, for
14 anyone to kind of get their heads around this
15 when you start looking at different models.

16 Just, again, I think you're
17 already well aware of this but NQF endorses
18 performance measures for accountability
19 applications and public reporting in addition
20 to improvement, the primary goal. But our
21 criteria apply to all applications. So
22 currently we don't have different criteria for

1 different use cases, for example.

2 And the other thing to keep in
3 mind is that NQF endorsement of the measure
4 includes all the specifications but not
5 reporting formats or presentations, for
6 example, on how it's displayed on the web page
7 for example. So, just to give you a little
8 context there. Next slide.

9 So in terms of our criteria about
10 risk adjustment you all know that we have a
11 criterion about validity. And one of the
12 elements under measure validity is for outcome
13 measures and other measures where it's
14 appropriate that there's an evidence-based
15 risk adjustment strategy. Typically this will
16 be statistical risk models, but occasionally
17 it'll be risk stratification and that's
18 something you'll see later today.

19 It should be based on factors that
20 influence the measured outcome but not factors
21 related to disparities in care or the quality
22 of care. They should be risk factors that are

1 present at the start of care and have
2 demonstrated adequate discrimination and
3 calibration.

4 Occasionally we do get outcome
5 measures that are not risk-adjusted. In that
6 case we'd want to see some rationale and data
7 analysis that supports that it doesn't need to
8 be risk-adjusted. Next slide.

9 So, you noticed that there were a
10 couple of little notes associated with that
11 criterion. These are the specific notes.
12 Risk factors that influence outcomes, we
13 prefer that they not be exclusions, that
14 they're actually in the risk model. And then
15 note 14 is that risk models should not obscure
16 disparities in care for populations by
17 including factors that are associated with
18 differences or inequalities in care.
19 Typically race and ethnicity are the ones most
20 thought of, but also socioeconomic status.
21 Occasionally gender is associated with
22 disparities.

1 And the whole point is that we're
2 trying to identify disparities and get rid of
3 them. So if we fold them into risk models
4 then it's hard to really know that we have
5 disparities going on and that we can do
6 something about them. So that's the NQF
7 perspective at this point in time. Okay, next
8 slide.

9 So, I'm just going to talk a
10 little bit high-level about statistical
11 approaches for risk adjustment. And in the
12 literature there seems to be emerging
13 consensus on the need to address the
14 correlation of clustered observations such as
15 patients within hospitals and also to
16 stabilize estimates of the performance. This
17 is sometimes called smoothing, sometimes
18 called shrinkage, sometimes referred to as
19 reliability adjustment. But this is
20 particularly an issue with small numbers.

21 Hierarchical models are
22 appropriate to address both of these issues.

1 However, even within hierarchical models there
2 are a variety of approaches. Even
3 occasionally you can have non-hierarchical
4 models that can address some of these issues.
5 But all of those have different assumptions,
6 strengths, weaknesses and practical
7 considerations. Coming back to, you know, NQF
8 has not dictated a specific statistical
9 approach.

10 And also, as you all have started
11 to look at the documentation for these
12 measures, I'm sure quickly saw that comparison
13 of those methods is very challenging. Next
14 slide.

15 So, I'm going to talk about the
16 CMS and AHRQ measures because those both have
17 statistical models. They both use
18 hierarchical approaches, they're both sound
19 approaches that are supported in peer-reviewed
20 literature and I think you also are aware of
21 a white paper on statistical issues for
22 performance measures. That was commissioned

1 by CMS from the Committee of Presidents of
2 Statistical Societies that specifically looked
3 at the hierarchical approach that CMS has been
4 taking with their mortality and readmission
5 measures. Next slide.

6 MS. JOHNSON: Karen, if we can
7 interrupt you just a second. Developers on
8 the line, if you would please mute your line,
9 please. We're hearing some feedback from your
10 lines.

11 DR. PACE: Okay, so the other
12 thing is that although CMS and AHRQ measures
13 are based on hierarchical approaches you
14 noticed as you were going through them that
15 they look different. And so I thought it
16 would be helpful to at least kind of identify
17 similarities and differences.

18 So both of them are addressing
19 correlation of clustered observations meaning
20 the patients within hospitals. Both of them
21 stabilized or smoothed the hospital rate based
22 on hospital-specific information in

1 combination with the national average. They
2 both used the national model that includes
3 only the patient-level factors as a comparison
4 in the denominator, and they both compute the
5 score for their measure as a rate. Next
6 slide.

7 So, where do we see the
8 differences is the modeling approach. So in
9 the CMS measure it's accomplished in one step
10 in the random effect hierarchical model. In
11 the AHRQ measure it's accomplished in two
12 steps. First, they used generalized
13 estimating equations for clustering and then
14 they do a reliability adjustment for
15 smoothing. So they're both addressing the
16 same issues, just in different statistical
17 approaches and stages. Next slide.

18 So, given that it would be
19 extremely difficult for us to ask you as a
20 steering committee to look at these two and
21 say, oh you know, one's better or somebody
22 should have done it differently. You know,

1 the question is what do we really ask the
2 steering committees to evaluate. And there's
3 many things that we need your expertise on.
4 Certainly our clinically relevant risk factors
5 that are associated with the outcome included
6 in the models. Are the risk factors those
7 things that are present at the start of care?
8 We don't want risk factors that are identified
9 during or after care. The risk factors should
10 not include those variables that are
11 associated with disparities.

12 In terms of the statistical model,
13 obviously you know was the statistical method
14 appropriate for the data. And were the model
15 performance metrics adequate. We do ask the
16 developers to provide information about how
17 the model is performing.

18 And I'll just make a note in terms
19 of risk stratification when we get to those
20 measures this afternoon or later this morning
21 I guess, you know, the items about the risk
22 factors are also applicable to stratification

1 variables. Those should be things that are
2 associated with different levels of risk. And
3 for stratification does an analysis
4 demonstrate the relationship of those
5 stratification categories to the occurrence of
6 the outcome. So we'll be looking at those
7 later this morning. And then next slide.

8 And finally, when you start --
9 after you've gone through the measures
10 individually and you actually start to look at
11 related or competing measures, you know, NQF
12 does prefer to endorse measures with the
13 broadest applicability, if possible to
14 identify the best measure from among competing
15 measures and certainly harmonized measures.

16 As I mentioned, there's currently no mechanism
17 to compare results using different statistical
18 approaches but some questions still remain for
19 the steering committee to consider. Are
20 multiple measures needed? You know, if
21 inpatient mortality is a subset of 30-day
22 mortality, for example, how do those two work

1 together? And if Medicare patients are a
2 subset of all patients. So those are some
3 questions for you to consider.

4 Secondly, are the specifications
5 and definitions of the outcome, the risk
6 factors, the target population and exclusions,
7 are those things harmonized across the
8 measures? And then, you know, certainly we
9 can have a discussion with the developers of
10 whether they've discussed their approaches to
11 identify the potential for and path to
12 achieving one measure or harmonized measures.

13 So with that I'm going to stop and
14 I know we have a lot to get into. But I'll
15 also just say as, you know, as you're going
16 through this process and you have any
17 suggestions for us about our criteria,
18 guidance to steering committees or information
19 that we should be requesting from developers
20 we would love to hear that. This is certainly
21 an area that's been difficult not just, you
22 know, for this steering committee but every

1 steering committee that comes up with outcome
2 measures. So I'll stop there.

3 MS. JOHNSON: Thank you very much
4 for that, Karen. Does anyone have any
5 questions real quickly for Karen before we
6 delve into the measures?

7 OPERATOR: For a comment or to ask
8 a question press * then the number 1 on your
9 telephone keypad.

10 MS. JOHNSON: Operator, this is
11 not for public comment right now.

12 MEMBER WADDY: So, I had first of
13 all a question about the definition of
14 disparities that you all are using. So at
15 least with the agreement between NIH and AHRQ
16 it includes rural versus urban disparities
17 which obviously would be pretty important when
18 you're trying to determine quality care across
19 the country. So my understanding is that
20 that's not included in your definition?

21 DR. PACE: We just gave examples.
22 We didn't have -- fully specify every type of

1 disparity. And I think the ones we identified
2 are the ones that typically get considered to
3 be put in as risk factors versus the
4 rural/urban because that's more at a higher
5 level than the patient level.

6 But you know, certainly, and I
7 think our disparities task force has probably
8 addressed that, but we just gave some
9 examples.

10 MEMBER WADDY: And then just
11 really quickly, I still am not entirely clear
12 how you handled disparities. Do you have an
13 example within what we're doing?

14 DR. PACE: It's a good question.
15 In terms of the risk models, generally we
16 don't want to see those variables in the risk
17 model unless there's good data and analysis
18 and evidence to indicate that they should be
19 in for a particular outcome or reason. So
20 that would be the exception rather than the
21 rule.

22 And in terms of whether it's

1 outcome measures or process measures we don't
2 currently -- what we're doing right now is
3 trying to identify measures that would be
4 disparity-sensitive so that they can be
5 reported to highlight these disparities. But
6 it's not generally been a part of every single
7 measure. So, Helen may want to elaborate on
8 that a little bit because I know she's been
9 involved with the disparities work.

10 DR. BURSTIN: I think that
11 captures it and we talked a little bit about
12 disparity sensitivity yesterday. So the idea
13 would be if you put race or ethnicity, for
14 example, into the risk model you then can't
15 stratify by it. And so the idea would be
16 instead to be able to see those differences
17 and stratify it, yes.

18 MEMBER KAPINOS: Can you go back
19 to your first slide when -- somewhere I read
20 that you did not validate your own risk model?
21 Somewhere it says like you do not have the
22 data to --

1 DR. PACE: No. What I was saying
2 is that NQF does not have a requirement first
3 of all or a mechanism. For example, for us to
4 take the, for example, the AHRQ and CMS risk
5 adjustment models, apply those to one data set
6 and come up with yes, this one's better than
7 that one.

8 First of all, even if we had a
9 common data set that we could run those models
10 we would still -- and they came up with
11 different results we would still have the
12 question of how would you know which result is
13 the better result. So what we're saying is
14 that right now you have to look at the
15 measures individually and the question really
16 is did the developer use an appropriate and,
17 you know, accepted method of doing risk
18 adjustment.

19 But right now we don't have the
20 capacity at NQF to say, you know, we don't
21 have a data set for example that we could tell
22 the developers you have to run your measures

1 and risk models on our data set so that we can
2 see a comparison.

3 MEMBER KAPINOS: Not on your data
4 set because you don't hold a data set of
5 course.

6 DR. PACE: Right. But we ask
7 every --

8 MEMBER KAPINOS: Why not asking
9 them to validate it first before they submit?

10 DR. PACE: Yes, yes, every --
11 that's part of our criteria, that the risk
12 model should be evidence-based and should
13 demonstrate adequate discrimination and
14 calibration. And that's why on the measure
15 submission form we've asked them to provide
16 that information to you. Okay?

17 MS. JOHNSON: Any other questions
18 for Karen? Okay, if not let's go ahead and go
19 into our meeting then. And I'm going to hand
20 it over to Dave.

21 CO-CHAIR KNOWLTON: We're going to
22 start with 0467. Therese?

1 MEMBER RICHMOND: This is a
2 currently endorsed measure, the Acute Stroke
3 Mortality Rate, which is -- the steward is
4 AHRQ. And it's a risk-stratified outcome
5 measure with data coming from administrative
6 records.

7 It looks at the proportion or the
8 percentage of hospital discharges with an in-
9 hospital death among cases with a principal
10 diagnosis of stroke, either ischemic or
11 hemorrhagic, for patients 18 years and older.

12 There are three exclusions:
13 transfer to another acute care hospital, MDC-
14 14 which is pregnancy/childbirth/puerperium
15 and missing key data, discharge, disposition,
16 gender, age, quarter or year of principal
17 diagnosis.

18 We had quite a juicy conversation
19 about this measure. And is the -- I don't
20 know if the developer is here, but we posed a
21 lot of questions to the developer. And you'll
22 see about a seven-plus page response to our

1 questions so thank you very much.

2 The impact, we'll start with
3 impact.

4 CO-CHAIR KNOWLTON: Before you go
5 on, I went out of order. I wanted to ask Dr.
6 Romano if he wanted to comment on his measure
7 before we started.

8 MEMBER RICHMOND: Sure.

9 DR. ROMANO: Yes, good morning.
10 This is Patrick Romano. I'm a general
11 internist and professor of medicine at UC
12 Davis School of Medicine in Sacramento. And
13 I'm here representing the Agency for
14 Healthcare Research and Quality.

15 I think on the phone with me is
16 John Bott from the Agency staff, Jeff Geppert
17 from Battelle Memorial Institute that leads
18 our analytic team, and Pat Zrelak from my team
19 at UC Davis who's a neuroscience nurse.

20 So, this -- I think you've really
21 summarized this measure. It is a currently
22 endorsed measure. It's one of a family of

1 measures that look at risk-adjusted inpatient
2 mortality for major medical conditions. There
3 are also very similar NQF-endorsed measures
4 for heart attack mortality, for pneumonia
5 mortality, heart failure mortality.

6 So, this measure is designed for
7 application with administrative hospital data
8 sets. It's designed for use with both state
9 data sets that state health data agencies have
10 as well as data sets that hospitals may use
11 internally or within hospital systems. So,
12 with that, thank you. CO-CHAIR KNOWLTON: Any
13 questions for Dr. Romano? Probably not yet.
14 Okay, impact, if you would please, Therese.

15 MEMBER RICHMOND: Great. This was
16 a criteria that actually our group -- we had
17 a group of four, three of whom voted. It had
18 agreement at either the high or moderate
19 level. We know there's a lot of strokes.
20 Mortality rate in the U.S. is about 17 percent
21 with the greatest risk of death in the first
22 30 days. And in 2008 almost half of stroke

1 deaths occurred in the hospital. So our group
2 rated this either as high or moderate.

3 CO-CHAIR KNOWLTON: Questions?
4 Comments? Vote on impact?

5 MS. THEBERGE: We have 19 high and
6 2 moderate.

7 CO-CHAIR KNOWLTON: Okay.

8 MEMBER RICHMOND: I guess we go to
9 evidence which we don't need to do for the
10 process, like the process measures but they
11 did need to make a link. And we agreed that
12 they made the link between structure, process
13 and outcome in terms of the outcome on
14 mortality. So our group also said yes to
15 that.

16 CO-CHAIR KNOWLTON: Questions?
17 Okay, let's vote.

18 MS. THEBERGE: Twenty-one yes,
19 zero no.

20 MEMBER RICHMOND: Okay. In terms
21 of opportunity for improvement or performance
22 gap we rated this either as high or moderate.

1 There was a variation in risk-adjusted rates
2 ranging from 73 per 1,000 to 136 per 1,000 and
3 there were variations across all categories
4 looked at, whether it was region of country,
5 type of hospital ownership, the teaching
6 status, the size of the city or the number of
7 beds in the hospital.

8 CO-CHAIR KNOWLTON: Questions or
9 comments? Okay, let's vote.

10 MS. THEBERGE: We're at 19 high, 2
11 moderate.

12 CO-CHAIR KNOWLTON: Okay. On to
13 reliability, scientific acceptability:
14 reliability 2a.

15 MEMBER RICHMOND: Okay, here comes
16 the seven-page response to our question. So
17 this is the juice of the discussion.

18 In terms of specification and
19 reliability two of us ranked this as high and
20 one with insufficient evidence. They use a
21 noise -- a signal-to-noise ratio of 0.776
22 which is very good. That is a weighted

1 average of reliability estimates across
2 providers and showing variations. So, I know
3 one of our group members had some questions.
4 I don't know if they were answered to your
5 satisfaction but reliability in general I
6 think we thought was high, yes.

7 CO-CHAIR KNOWLTON: Questions or
8 comments? Okay, we can vote on that.

9 MS. THEBERGE: We are at 17 high,
10 4 moderate.

11 CO-CHAIR KNOWLTON: Validity.

12 MEMBER RICHMOND: Okay, validity.
13 In our telephone conversation one of us ranked
14 this as low and two, insufficient evidence.
15 Thus we posed a lot of questions to the
16 developer and you saw both an updated form as
17 well as a seven-page response. So there
18 really are three things to look at here. One
19 is the establishment of validity, the impact
20 of threats and the risk adjustment. And I'll
21 just say a little bit about each and then we
22 can talk.

1 I will say that, and I was an
2 insufficient evidence and they provided a lot
3 of evidence that I'm much more comfortable
4 with. This was looked at in terms of face
5 validity with an expert panel but really the
6 substance is a criterion validity. They
7 established for both the denominator, are we
8 picking up a stroke diagnosis, comparing the
9 administrative data to a gold standard chart
10 abstraction with very good sensitivity and
11 specificity. And also they provided
12 additional information on the numerator in
13 terms of picking up stroke mortality in the
14 hospital.

15 They tested their models also with
16 the exclusion of transfer, with and without
17 transfers from acute care hospitals and found
18 no statistical difference. A lot of the
19 questions really centered around risk
20 adjustment and they used, I think the
21 introduction was really helpful in terms of
22 they do use a hierarchical model, logistic

1 regressions and GEE to deal with clustering,
2 include covariates for gender and age, and
3 then use a system that I think is a
4 proprietary system but the logic is available
5 of APR-DRGs which is an all-patient refined
6 diagnosis-related groups that includes a
7 severity measure that -- and a risk-for-
8 mortality measure. So it really includes that
9 in the modeling. And the severity measures is
10 defined as the extent of physiological
11 dysfunction or organ system loss or function.

12 We asked a lot of information on
13 this and specifically what was -- how it was
14 done and what was included in the model. And
15 for the most part my questions were answered
16 by that. They have a C statistics for the
17 risk model and the development sample of 0.86
18 and the validation sample of 0.89.

19 I'm going to ask my other group
20 members to jump in here because we had so many
21 questions on the risk adjustment if I could.

22 CO-CHAIR KNOWLTON: Sure. Other

1 group members on this issue? Risha?

2 MEMBER GIDWANI: Good morning. I
3 had a couple of different questions. I posed
4 a number of them during the original work
5 group call but the developers did a wonderful
6 job actually of responding to those.

7 The ones that I have remaining I'd
8 like the developers to confirm that the
9 coefficients they're presenting are log odds.
10 Is this correct?

11 MR. GEPPERT: Yes, that's correct.
12 I'm sorry, this is Jeff Geppert from -- that's
13 correct. Yes.

14 MEMBER GIDWANI: Okay. A
15 recommendation for the future is to actually
16 present these in terms of probabilities. Log
17 odds are actually quite difficult to
18 interpret, so to either exponentiate them as
19 odds or to use actual probabilities.

20 In terms of the APR-DRGs there's a
21 risk of mortality and that's the last digit in
22 that four-digit number under "Label." And I'd

1 also request the developers to confirm that
2 these APR-DRG risk of mortalities are actually
3 for the admission status rather than the
4 discharge.

5 DR. ROMANO: Yes, that's correct.
6 They're based on the diagnoses that were
7 present on admission.

8 MEMBER GIDWANI: Okay, great.
9 Thank you. And then just a couple of other
10 things.

11 One, the APR-DRGs are a black box.
12 3M owns this methodology and they do not
13 provide the details of how risk of mortalities
14 are calculated to anybody. So a suggestion is
15 to move in the future away from a methodology
16 that has a black box associated with it and to
17 go towards something more transparent.

18 And then finally I would like to
19 ask the developers whether there is a
20 rationale for -- or if there's a thought
21 towards excluding EMTALA patients who may be
22 at higher risk of mortality yet the hospitals

1 are not able to turn these patients away.
2 They're coming in through the ED. And whether
3 this would actually unfairly ding hospitals
4 that see a lot of EMTALA patients.

5 CO-CHAIR KNOWLTON: Dr. Romano?

6 DR. ROMANO: I'm sorry, how would
7 you identify or define EMTALA patients?

8 MEMBER GIDWANI: Well, I'm not
9 sure if there's a billing code for that, but
10 there is no status of whether the patient came
11 in through the emergency department and what
12 that patient's level of severity was when
13 coming in through the ED. So there's not even
14 an ability to understand whether they came in
15 through Life Flight or ED which would render
16 them at higher risk of mortality.

17 DR. ZRELAK: This is Pat Zrelak
18 from the UC Davis team. The majority of your
19 stroke patients will come in through your
20 emergency department.

21 DR. ROMANO: Right, the greater
22 majority are ED admissions. I'm afraid

1 there's no data element that would
2 specifically distinguish those who might be
3 classified as EMTALA patients or those who
4 would be brought in by helicopter.

5 With reference to your first
6 comment, I believe that Dr. Goldfield is on
7 the line but there's actually a limited
8 license agreement between AHRQ and 3M that
9 effectively puts the components of the APR-DRG
10 system that are necessary for risk adjustment
11 to this indicator into the public domain. And
12 I'll ask Dr. Goldfield or Dr. Geppert to
13 comment on that further.

14 DR. GOLDFIELD: I'm on the line.
15 Maybe Rich Averill who's also on the line
16 could say specifically exactly on that point.
17 So I appreciate being asked because in fact I
18 would have to differ with the assertion that
19 it's a black box.

20 MR. AVERILL: We have a website
21 that's APR sign with a login. And anybody who
22 wants to inspect the complete APR risk of

1 mortality logic can request a copy of that and
2 at no cost can fully inspect all aspects of
3 the logic. We encourage people to do that.
4 We solicit comments and that is part of our
5 annual update process.

6 DR. GOLDFIELD: And I just would
7 like to add -- this is Norbert Goldfield
8 speaking -- just briefly, I don't want to take
9 too much time, is that the critical aspect
10 which is why the APR-DRGs are extremely widely
11 used is the fact that it's a categorical model
12 and clinicians drill down, right down to the
13 individual patient level. And that's also why
14 we encourage --

15 CO-CHAIR KNOWLTON: Would you
16 speak up please on the phone? It's hard to
17 hear you in the meeting room. Just speak up
18 a little.

19 DR. GOLDFIELD: Can people hear me
20 now?

21 CO-CHAIR KNOWLTON: Yes, that's
22 much better. Thank you.

1 DR. GOLDFIELD: I was just making
2 the point that the APR-DRGs are a categorical
3 clinical model which means that similar but a
4 different model to the MS-DRGs but applied to
5 all patients. The clinicians can drill down,
6 right down to the individual patient and see
7 exactly for that patient why the person was
8 assigned to a particular severity level which
9 is why we encourage strongly individuals to
10 not only access the model but provide feedback
11 and sort of a consequence. It's not a black
12 box, but appreciate the opportunity to
13 comment.

14 CO-CHAIR KNOWLTON: Risha?

15 MEMBER GIDWANI: Thank you, I
16 wasn't aware of that. I wasn't able to
17 actually access information on how the APR-DRG
18 risk of mortality was assigned so I'll look
19 into that if that is available publicly.

20 I still, however, do have a
21 concern. I think generally these models are
22 doing a good job but if they are able to

1 account for Life Flight patients or EMTALA
2 patients due to a lack of billing codes I see
3 that that, you know, poses a logistical
4 difficulty but in terms of actually accounting
5 for risk of mortality the models wouldn't be
6 able to do that. So it's one component that
7 is not present here.

8 CO-CHAIR KNOWLTON: Can I ask you
9 a question, Risha? When you're talking about
10 an EMTALA patient you're not just talking
11 about insurance status. That's really the
12 issue, is that not true?

13 MEMBER GIDWANI: Well, these are
14 patients that are coming into the emergency
15 department that cannot be turned away because
16 they are, you know, having a true emergency.

17 CO-CHAIR KNOWLTON: But the basis
18 for turning them away would be that they do
19 not have insurance or in some way cannot
20 afford the care. Because other than that as
21 I think has been pointed out all of them, or
22 not all of them but a majority of them are

1 coming in through the ER.

2 So what differentiates an EMTALA
3 from a non-EMTALA is merely the ability to
4 pay. That would be the only reason that you
5 would activate EMTALA would be that you have
6 to treat them under the EMTALA law because
7 they don't have the ability to pay.

8 MEMBER GIDWANI: Right and --

9 CO-CHAIR KNOWLTON: And I wonder
10 back to our risk stratification issue that
11 Karen talked about, if we would be -- want to
12 apply a risk factor in advance that has to do
13 with that factor.

14 MEMBER GIDWANI: I think that's an
15 interesting point. I think there's also other
16 risk factors associated with lack of insurance
17 that may be putting these patients at higher
18 risk of mortality.

19 CO-CHAIR KNOWLTON: Okay. David
20 and then Bill.

21 CO-CHAIR TIRSCHWELL: So I had a
22 question for the developers and maybe you can

1 just confirm this. I think you already said
2 the severity measures are all based on
3 present-on-admission characteristics. But I
4 mean are there symptom-specific present-on-
5 admission characteristics like coma or
6 something like that that gets you severity?
7 And I see Dr. Romano is nodding his head. So
8 I'll take that as a yes. And specifically
9 complications are not included, things like
10 pneumonia and things like that. He's nodding
11 yes again.

12 But then the part two of my
13 question, I know that you've checked for
14 reliability as to identification of patients
15 and such, but at the end of the day your
16 models theoretically allow you to rank
17 hospitals. And my question is have you taken
18 this model which gives you a set of rankings
19 and then compared a set of rankings to a gold
20 standard patient database where there is
21 detailed clinical information about patients.
22 NIH Stroke Scale Scores, you know, chart-

1 abstracted comorbidities, a much -- obviously
2 more expensive approach to predicting outcome
3 but what I think most people would think of as
4 a gold standard, and shown that the ratings
5 are essentially highly correlated.

6 DR. ROMANO: We agree that that
7 would be an important thing to do and in fact
8 we've started having some discussions with the
9 Get With the Guidelines group, American Heart
10 Association group about -- they have as you
11 probably know a linked data set with Medicare
12 claims as well as registry data with detailed
13 physiologic information and the NIH Stroke
14 Scale. So we are hoping to use that
15 information as kind of a laboratory for
16 testing the comparative model.

17 They published a paper which you
18 may have seen suggesting that the
19 administrative data didn't perform nearly as
20 well as models with NIH Stroke Scale. But the
21 C statistic on the model that they were
22 testing was in the range of 0.65 as I recall

1 whereas the C statistic on our model is close
2 to 0.9. So it's a substantial gap in
3 performance there. So we would hope that that
4 would narrow the discrepancy in the kind of
5 comparative analysis that you're describing
6 but we haven't empirically tested that.

7 What we have empirically tested
8 that I could comment on in follow-up to the
9 comments. One is that there was some concern
10 about the fact that the APR-DRG risk
11 adjustment does incorporate some information
12 about procedures that are performed during the
13 hospital stay. And that could be construed as
14 a violation of the NQF principles that Karen
15 described.

16 So for example, if a patient has a
17 hemorrhagic stroke and they require a
18 craniotomy for evacuation of the hematoma then
19 that craniotomy goes into the risk adjustment.
20 And it is an important factor in the risk
21 adjustment in terms of the likelihood
22 function, but we've actually -- in follow-up

1 to the discussion we tested models without
2 those variables and we showed that the C
3 statistic is essentially unaffected, that it
4 remains about 0.9 without those procedure-
5 based APR-DRGs. And furthermore the
6 correlation in a provider rate between models
7 with and without those procedure-based APR-
8 DRGs is 0.978.

9 So basically although those
10 procedure factors are correlated with the
11 expected mortality rate and with the observed
12 mortality rate, they don't actually explain
13 variation across hospitals. So they serve as
14 proxies for stroke severity essentially. So
15 having said that, they -- we could basically
16 go either way in terms of including those
17 factors or not.

18 The other thing that I should say
19 that we tested in terms of a gold standard
20 analysis is using the California state data
21 set where we had the ability to look at 30-day
22 mortality as well as inpatient mortality. We

1 re-estimated the risk adjustment model using
2 the California data set, again demonstrated a
3 very high C statistic of 0.863. And looking
4 at the correlation, the weighted correlation
5 of risk adjustment inpatient versus 30-day
6 mortality at the hospital level, that
7 correlation was 0.64. So that's in the
8 moderate range.

9 CO-CHAIR TIRSCHWELL: That's r-
10 squared or just r?

11 DR. ROMANO: That is r.

12 CO-CHAIR TIRSCHWELL: So then your
13 r-squared is only 0.3 so you're only
14 explaining about 40 percent of the variation
15 in the 30-day mortality with your inpatient
16 model which doesn't seem fantastic to me.

17 DR. ROMANO: Correct. So there is
18 some difference between inpatient and 30-day
19 mortality measures. What we and others have
20 demonstrated is that there's more hospital-
21 level signal. So if you look at what we call
22 the intra-class correlation coefficient, the

1 hospital-level signal there's more signal
2 looking at inpatient mortality which of course
3 makes sense because it's more a reflection of
4 what happens in the hospital, less affected by
5 what happens after the patient is discharged.
6 But it does potentially introduce the
7 possibility of bias related to variation in
8 transfer practices and length of stay across
9 hospitals.

10 CO-CHAIR TIRSCHWELL: Yes, I mean
11 the objection that was raised was that
12 hospitals whose practice is to discharge all
13 comfort care patients to a nursing home to die
14 will artificially look like they're performing
15 better, whereas the 30-day mortality measure
16 would even that out theoretically.

17 And you know, part of my
18 impression of the big difference between your
19 model and for example the one you referred to
20 in Get With the Guidelines, and I'm not 100
21 percent sure about this, is that they limited
22 their analysis to ischemic strokes. And by

1 having the three subtypes of stroke in your
2 model my guess is that the vast majority of
3 your explanatory power is based on the fact
4 that you can separate hemorrhages with their
5 much higher mortality rates from ischemic
6 strokes with a much lower mortality rate.

7 And I think you'd find shocking
8 differences in your C statistics if you
9 stratified your model by stroke type. In
10 fact, I think your performance would radically
11 fall in your C statistic if you looked at the
12 model for each stroke type separately.

13 So, you know, I think this is an
14 amazing thing to do and have out there. The
15 fact that God knows how much money AHRQ has
16 spent on this measure already and the fact
17 that you haven't spent, you know, probably a
18 relatively small amount of money to validate
19 it against a high-quality, carefully
20 abstracted set of patient-specific data is a
21 little disappointing.

22 CO-CHAIR KNOWLTON: Michael?

1 MEMBER KAPLITT: So, you know,
2 along the lines of I guess this or the EMTALA
3 question. I was looking at various
4 stratifications and unless I'm not seeing it
5 why is there no discussion of transfers as an
6 issue like either in or out? Because along
7 the same lines -- so if you're a hospital that
8 transfers out a lot of patients with
9 hemorrhages to my hospital, we operated on
10 them, they die. Our hospital looks like we
11 don't do very well with strokes, your hospital
12 looks like you're great and then everybody
13 wants to go there but that's because you're
14 transferring out all the people that are sick
15 to my hospital. Right? So how is that
16 accounted for and why isn't that? Or is it
17 and I'm not seeing it?

18 DR. ROMANO: We do routinely test
19 for transfer in as a risk factor for
20 mortality. And we find that in some patient
21 cohorts it's a significant risk factor and in
22 others it's not. In this particular model

1 actually it didn't enter the model. I'm not
2 sure, Jeff, do you have any additional comment
3 on that?

4 MEMBER KAPLITT: Before you answer
5 I would also ask about transfers out because
6 I would think that's equally relevant. You
7 know, if somebody's actually doing better
8 because they're transferring a
9 disproportionate number of patients I would
10 think that should be in the model.

11 DR. ROMANO: Well, remember that
12 this measure is designed for hospitals
13 themselves to use, hospital systems, state
14 health data agencies, regional coalitions,
15 other entities that don't have the ability to
16 link data across hospitals. So, therefore the
17 patients who are transferred out are excluded
18 from the analysis because we don't know what
19 their outcome status is at the time that they
20 leave the acute care center. So those
21 patients are excluded from both the numerator
22 and the denominator.

1 MEMBER KAPLITT: That I
2 understand. I'm just saying that like later
3 we're going to be asked in one of the later
4 sections about the potential for misuse, let's
5 say, or problems or whatever in one of the
6 later things and we know that there are plenty
7 of areas. If you look at the history of let's
8 say cardiac surgery testing or whatever, when
9 these things get implemented there are some
10 incentives for certain institutions to, you
11 know, not treat patients that are sick or
12 transfer them out. And I would think that in
13 order to disincentivize that, that should be
14 somehow included in the model, you know,
15 equally to transfers in.

16 MR. GEPPERT: We have in fact
17 tested hospital-level models where we used
18 transfer-out percentage as a factor in the
19 model and it doesn't have explanatory power in
20 those hospital-level models relative to other
21 things, other characteristics of the hospital
22 like their volume or their capacity.

1 CO-CHAIR KNOWLTON: Salina.

2 MEMBER WADDY: I agree with
3 Michael's point. That's exactly what we've
4 been sitting here discussing.

5 I do think it would be very
6 interesting to know down the line if when this
7 is implemented for -- or if this is
8 implemented through this as well as in the
9 past few years that they've had the original
10 endorsement whether or not that actually
11 changes what hospitals potentially do in terms
12 of how they handle the -- handle the
13 transfers.

14 The other thing is what happens to
15 the patients. And this happened frequently
16 when I was at Emory. Patients that were
17 transferred out but they did not end up being
18 admitted at the other hospital, at the
19 receiving hospital because of death en route.

20 CO-CHAIR KNOWLTON: Ramon?

21 MEMBER R. BAUTISTA: This is a
22 very important measure. In fact, it probably

1 is the sole measurement that might make or
2 break many stroke centers.

3 It's also a reevaluation of a
4 measure we actually saw in 2008. So similar
5 to the stroke education measure from yesterday
6 I think the committee should demand evidence
7 of it being used properly out there before
8 approving it for re-implementation again.
9 Otherwise we're unfairly penalizing some
10 stroke programs and that would be very bad for
11 them.

12 CO-CHAIR KNOWLTON: Daniel?

13 MEMBER LABOVITZ: I think this is
14 a corollary to what Ramon just said. But I
15 think death as a measure of quality is a
16 really complicated area. I'm not sure --
17 death is not a common stroke outcome. Stroke
18 is I guess now the fourth leading cause of
19 death, but those deaths don't occur in the
20 hospital.

21 I think what hospitals do with
22 patients who are near the end of life or at

1 the end of life can range widely in quality.
2 And I've worked in a few different New York
3 City area hospitals. One of the hospitals
4 that does the best on death does the worst on
5 compassion.

6 I think we could really drive --
7 we could really go the wrong way here with a
8 measure that is based on administrative data.
9 And I would be very, very reluctant to put a
10 stamp of approval on that.

11 CO-CHAIR KNOWLTON: Bill?

12 MEMBER BARSAN: I just have a
13 question for the developer again. So the
14 question was asked about the transfers in and
15 I think you -- what I took from that is that
16 you use the transfer things for different
17 measures but not for this one? Is it used for
18 this one or not?

19 DR. ROMANO: It was not
20 statistically or clinically significant in the
21 model for this measure so it was excluded from
22 the model.

1 MEMBER BARSAN: So you don't use
2 it.

3 DR. ROMANO: Correct.

4 MEMBER BARSAN: Okay.

5 CO-CHAIR KNOWLTON: Risha?

6 MEMBER GIDWANI: I also have a
7 question about patients who are on DNR or DNI
8 status. And I understand that that's not
9 accounted for in this model either, is that
10 correct?

11 DR. ROMANO: That's correct.
12 There is a data element that's been introduced
13 in some states and we're doing some
14 exploratory testing using that data element
15 but there's obviously some concern about when
16 the order is written, whether the order is
17 written after some deterioration of the care
18 of the patient as well as variation across
19 hospitals.

20 So again, getting back to the
21 methodologic concerns that Karen raised, we
22 want to make sure that that in itself is not

1 a quality issue before we include it in the
2 risk adjustment model.

3 MEMBER GIDWANI: I'm not a
4 clinician so correct me if I'm wrong, but
5 isn't it the patient and/or family decision to
6 be a DNR or DNI?

7 DR. GOLDFIELD: Could I just
8 comment on that? This is Norbert Goldfield.
9 I just want to say in addition there's a lot
10 of literature on this point. In fact, one
11 reason to be very careful about the DNR is
12 because of practice pattern variation. When
13 Patrick was referring to the hospital the
14 hospital is clearly composed obviously of
15 patients and their families and physicians,
16 and there's a lot of practice pattern
17 variation in terms of preferences. And one
18 just has to be very careful about
19 incorporating that into the risk model. All
20 right, Patrick.

21 MEMBER GIDWANI: But what we're
22 talking about incorporating is not physician

1 preference, we're talking about incorporating
2 patient and family preference.

3 DR. GOLDFIELD: To put it simply
4 that information is not available today. A
5 and B as you probably know, again the
6 literature is quite clear on that point too.
7 It's not -- that's not done in a vacuum. That
8 very much can be impacted by provider
9 preference or professional preference.

10 CO-CHAIR KNOWLTON: Are you done,
11 Risha?

12 MEMBER GIDWANI: Yes.

13 DR. ROMANO: And it's also been
14 documented that in many cases the DNR orders
15 are written after some events happen in the
16 hospital. So it may in fact be a marker for
17 deterioration of the patient after admission
18 to the hospital.

19 MEMBER KAPINOS: Actually and to
20 clarify about that, it shouldn't be only
21 looking at the DNR/DNI because actually
22 palliative care specialists and the people who

1 work in ICUs have tried to -- recently tried
2 to separate the whole concept of do not
3 resuscitate as opposed to goals of care. So
4 we shouldn't be talking about DNR because
5 DNR/DNI just means do not resuscitate upon a
6 cardiac or a respiratory arrest as opposed to
7 what we are all discussing is the decisions of
8 how aggressive should be the level of -- how
9 aggressive should be the goals of care. So we
10 should reformulate this discussion about not
11 DNR/DNI but actually the level of aggressivity
12 of the goals of care. That's actually a more
13 proper terminology.

14 And to answer your question,
15 actually no, it's not -- I mean a lot of
16 ethicists, I mean Bernard, you know, like the
17 famous -- the trial on the cardiac arrest
18 recently also published in Neurology, the fact
19 that actually the more you offer to patient
20 family members the opportunity to consent or
21 to give their opinion on should the patient be
22 resuscitated or not, the more guilt you

1 trigger in those family members.

2 And actually more -- many
3 palliative care physicians are actually saying
4 that DNR/DNI is based more on if you think as
5 a physician that the patient should not be
6 resuscitated you should not ask a question to
7 the family members, but you tell them that you
8 think it does not make sense to fight for such
9 a low quality of life.

10 So I just want to make sure that
11 people don't look at the issue of DNR/DNI as
12 a black and white thing. I think it's more
13 goals of care and it's more gray with many
14 shades as opposed to just something that's
15 going to be easily measurable.

16 CO-CHAIR KNOWLTON: Jolynn?

17 MEMBER SUKO: Yes, I just wanted
18 to present a counterpoint to Daniel's argument
19 around outcome. And I think that is that yes,
20 there's many variables that lead to death but
21 if we're not looking at outcome we're not
22 going to be able to identify those

1 institutional level variables that may
2 contribute to quality and how we organize
3 care.

4 We know in many situations for
5 clinical conditions there's a relationship
6 between volume and outcome. And I think that
7 there's no performance measure that's going to
8 be perfect. And so yes, there's a risk of
9 misuse but there's also a risk of not looking
10 and not continuing to draw on those questions
11 by not endorsing an outcome measure.

12 CO-CHAIR KNOWLTON: Gail?

13 MEMBER COONEY: I think I just
14 retracted my comment.

15 CO-CHAIR KNOWLTON: Okay. David?

16 MEMBER HACKNEY: I'm going along
17 with Jolynn on the importance of looking at
18 outcome measures, but what I'm worried about
19 is it's going to be almost impossible to
20 interpret this one. You'll get data but you
21 won't know what it means and it could be
22 highly misleading and point you in the wrong

1 direction about which hospitals and practices
2 are doing well and which are doing poorly. So
3 I'm -- without knowing what the results mean
4 I don't know how we can endorse a measure.

5 CO-CHAIR KNOWLTON: Michael?

6 MEMBER KAPLITT: So, you know, I'm
7 sorry to belabor this point but I know you
8 said, and that's a good answer, that you know,
9 you looked at transfers and it wasn't
10 significant. But as David said earlier you're
11 looking at multiple different stroke types,
12 not just ischemic stroke.

13 Did you look at transfer issue by
14 stroke type? And the reason I ask that is
15 that let's say one hospital has 1,000 ischemic
16 strokes and 10 hemorrhagic strokes, and they
17 transfer all 10 to my hospital. My hospital
18 also has 1,000 ischemic strokes but I take all
19 10 hemorrhagic strokes because I have
20 neurosurgeons and they don't. Nine of those
21 ten die because they have the higher mortality
22 rate so that my mortality rate's going to be

1 higher because of those 10 people but it's not
2 going to show up statistically in the entire
3 population because it's being washed out.

4 So, have you looked at it that
5 way? Because I just don't want hospitals that
6 have certain level of care that's actually
7 providing better care to be penalized because
8 they're taking what represent the majority of
9 the deaths with the minority of the transfers.

10 DR. ROMANO: Okay, so I think
11 you're suggesting an interaction or effect
12 modification between the type of stroke and
13 whether the patient is transferred in. Jeff?

14 MEMBER KAPLITT: Transfers of the
15 type --

16 DR. ROMANO: To my knowledge we
17 have not looked at that. The model does
18 stratify risk of mortality separately by
19 hemorrhagic versus ischemic stroke. So there
20 is the opportunity for different risk factors
21 to affect the risk of mortality for
22 hemorrhagic versus ischemic stroke but that

1 does not apply. That applies to clinical risk
2 factors such as the coma at presentation and
3 so forth. Doesn't apply to transfer status.

4 Jeff, do you have anything to add
5 to that?

6 MR. GEPPERT: Just to go back to
7 the earlier comment about whether the
8 explanatory power was due to the inclusion of
9 both stroke types. And we did test that. We
10 examined our C statistic separately for each
11 stroke type.

12 Patrick, do you happen to have --

13 CO-CHAIR KNOWLTON: Let's not go
14 back and forth on the measure. We're getting
15 into the weeds deeper and deeper, so let's
16 focus on what the committee has as questions.
17 Risha?

18 MEMBER GIDWANI: I'm sorry, I
19 think that's actually important. I would like
20 to hear the C statistic that the developer --

21 CO-CHAIR KNOWLTON: Well, then ask
22 the question again.

1 MEMBER GIDWANI: Okay, I'll just
2 ask the developer. Can you please continue
3 and present the C statistic for the models
4 when you disaggregated by stroke type?

5 MR. GEPPERT: I was just going to
6 ask Patrick if he happened to have those
7 results with him handy. Otherwise I'll find
8 them quickly.

9 But my recollection was that there
10 was a slight drop in the C statistic but they
11 were comparable. It was maybe like a 0.7 or
12 0.8, in that range, rather than a 0.9,
13 something like that.

14 MEMBER GIDWANI: Well, a 0.7 is
15 pretty different than a 0.9 so if we could
16 actually get that statistics that would be
17 great.

18 MR. GEPPERT: If I can't find it
19 now we'll provide it to the committee later.

20 CO-CHAIR KNOWLTON: Do you know
21 have another point while --

22 MEMBER GIDWANI: I do. I do. I

1 am actually quite comfortable with the C
2 statistic of 0.9 that the model developers are
3 presenting. But to get at this question of
4 whether there are going to be some issues of
5 model fit when we're looking at the extremes
6 of the types of patients, did the model
7 developers do a Hosmer-Lemeshow test? And if
8 so, can you present those results?

9 MR. GEPPERT: We run that test
10 because we have so much data it always rejects
11 so it's not a particularly -- we don't find it
12 to be a particularly useful diagnostic. So we
13 tend to look at the risk decile charts.

14 DR. PACE: And that's consistent
15 with what our -- some previous expert panels
16 have told us about the Hosmer-Lemeshow
17 statistic. And they did provide the risk
18 decile plots for you in the response in terms
19 of looking at the calibration of -- and that
20 was in the responses from AHRQ.

21 CO-CHAIR TIRSCHWELL: It's in the
22 Final Measures folder. And I think it's got

1 the --

2 DR. PACE: Suzanne, can you bring
3 it up on the?

4 DR. ROMANO: Could I address one
5 of the other questions?

6 DR. PACE: Yes, go ahead.

7 DR. ROMANO: So, I just wanted to
8 say that we certainly agree with the
9 importance of compassion and with the
10 importance of other stroke measures. So this
11 committee is considering and NQF has
12 previously endorsed many other measures of
13 stroke quality. This is certainly just one
14 measure of what would be a comprehensive
15 dashboard of measures related to stroke
16 mortality which should certainly include
17 measures related to patient experience and
18 ideally functional outcomes as well.

19 This measure has been in use for 4
20 years with NQF endorsement. So I think you
21 might look to the experience or lack thereof
22 in terms of whether a measure has been misused

1 in leading to pernicious practices. We're not
2 aware of that experience but we certainly
3 would like to learn about it if committee
4 members are aware of that kind of misuse of
5 the measure.

6 CO-CHAIR KNOWLTON: Is there
7 evidence of use for productive purposes? I
8 guess I'm not aware of use in either direction
9 quite honestly. From what Dr. Bautista was
10 suggesting which seems reasonable 5 years
11 hence, 4 years hence where's the evidence this
12 is driving practice in a positive direction?

13 DR. BOTT: This is John Bott with
14 AHRQ. And we did a series of user group
15 meetings a couple of years back. We called it
16 a Learning Network. And this measure was used
17 as a case-in-point by a hospital coalition in
18 Texas where they used this measure with the
19 70-plus hospitals in their association, found
20 out what was driving mortality in some
21 hospitals related to stroke and made
22 improvements. I looked at the PowerPoint this

1 morning. They talked about it. They didn't
2 have particular PowerPoints in that slide.
3 That's at least one example.

4 DR. ZRELAK: This is Pat Zrelak
5 again from the AHRQ team. And one of my other
6 roles is to actually run the UC Davis stroke
7 program. And so we do look at our stroke
8 mortality and we're a hospital that has very
9 high uninsured, very difficult stroke
10 population. And we have a fairly high stroke
11 mortality. And so I look at it right when I
12 do my annual quality report, the hospital
13 quality department, they want to hear about
14 our stroke mortality and what we're doing to
15 improve it. And when I do pull those cases
16 and drill down there is a lot of opportunity
17 there for improvement.

18 CO-CHAIR TIRSCHWELL: Are you
19 calculating your AHRQ mortality ratio and
20 putting it in perspective or are you just
21 looking at your hospital stroke mortality
22 cases which are obviously two totally

1 different things?

2 DR. ZRELAK: I do both. I use the
3 AHRQ measure a lot for benchmarking so I can
4 compare myself mainly against other university
5 hospitals because I for the most part use the
6 University Health Consortium measures. So I
7 do both.

8 CO-CHAIR KNOWLTON: Ramon, then
9 Risha.

10 MEMBER R. BAUTISTA: Let me just -
11 - a counterpoint to the counterpoint. I mean,
12 of course we would like to have a mortality
13 measure. Of course we'd like to have a good
14 education measure. But it has to be done
15 well. And again, this is a reevaluation of an
16 old measure. Unless done right I just feel
17 that we will have negative consequences that's
18 going to really hurt more people than help.

19 CO-CHAIR KNOWLTON: Risha?

20 MEMBER GIDWANI: I'm looking at
21 the risk deciles that the developers provided
22 and there are no values for the y axis so it's

1 difficult to understand what the difference is
2 between observed and predicted.

3 CO-CHAIR TIRSCHWELL: It says
4 mortality rate.

5 MEMBER GIDWANI: I can't see --

6 CO-CHAIR TIRSCHWELL: You don't
7 know what the absolute values are.

8 MEMBER GIDWANI: Right, I just --
9 I don't know what that means. On the printout
10 it shows. Okay.

11 And then the other thing is I'm
12 looking at this same document. And in this
13 document I also asked for an explanation of
14 how x is an improved vector of binary
15 explanatory variables compared with z. The
16 response, if you scroll down you'll see it on
17 this larger screen as well, the response is
18 that x are covariates based on all secondary
19 diagnosis codes while z are covariates based
20 on secondary diagnosis codes that are coded as
21 present on admission.

22 I'm unclear from this response,

1 I'm not sure if this was a miswording. Are
2 you actually using covariates that are also
3 not present on admission?

4 MR. GEPPERT: Just to address that
5 question. So if the data has present-on-
6 admission data elements on it and they are
7 using coded present-on-admission data then no,
8 we're not using covariates that do not use
9 present-on-admission. If that's clear.

10 MEMBER GIDWANI: I'm sorry, I
11 can't understand that. Are you using x as the
12 model, as the predictor variables, or z as
13 predictor variables?

14 MR. GEPPERT: We're using x which
15 is the version of the predictor variables that
16 uses the present-on-admission data.

17 MEMBER GIDWANI: That's not what's
18 noted here in your response.

19 MR. GEPPERT: It might just be
20 inverted, but x is the version that uses the
21 present-on-admission data. Z is the version
22 that does not. And we're using x.

1 MEMBER GIDWANI: Okay.

2 CO-CHAIR KNOWLTON: Helen?

3 DR. BURSTIN: I just want to make
4 one point that we're still on validity. So
5 many of the issues we've now stumbled into,
6 they're really important, are usability. And
7 I just want to make sure we keep our
8 conversation separate. There's actually a
9 great deal of detail under the usability
10 section about current use. So.

11 MEMBER SUKO: Yes, I just wanted
12 to speak to the use of outcome measures. And
13 I can say that in the organization where I
14 work we do actually look at our mortality. We
15 go in and we'll do chart reviews on different
16 clinical diagnosis. And we've actually -- we
17 do. Oh, well I was responding to the outcome
18 question.

19 CO-CHAIR KNOWLTON: Go ahead,
20 finish.

21 MEMBER SUKO: Okay. So we do
22 actually and we have discovered -- we've

1 discovered residents who had some
2 opportunities for learning improvement in how
3 they do things and how they document things.
4 And so we have used outcome data. And we've
5 also discovered documentation errors or things
6 that were more administrative in nature.

7 And so while you can't say that
8 it's always a clinical process that's gone
9 wrong or an error in judgment by a provider
10 you do discover things that lead to better
11 management of patients.

12 CO-CHAIR KNOWLTON: Anybody have
13 anything -- Therese, do you have anything
14 else? We are on the issue of validity, okay?
15 Everybody remember that from way back then?
16 Are you ready? Let's vote. The issue is
17 validity.

18 MS. THEBERGE: Two high, ten
19 moderate, six low, four insufficient evidence.

20 CO-CHAIR KNOWLTON: Okay, we move
21 on. Therese?

22 MEMBER RICHMOND: Whoa. Okay, now

1 we're up to usability. Our group ranked this,
2 not surprisingly, one high, one low, and one
3 insufficient evidence.

4 In terms of usability there are 18
5 states or systems that are said to publicly
6 report this although not all of them when you
7 go into the systems actually report stroke
8 outcome, but many do. And it's also used in
9 the Commonwealth Fund, Why Not the Best and
10 Monarch. It's used for quality improvement by
11 the University Health Consortium and in the
12 Premier Quest tool. So we were across the
13 board as a group.

14 CO-CHAIR KNOWLTON: Thoughts,
15 comments? Jolynn, is your hand up? No.
16 Risha?

17 MEMBER GIDWANI: I was the work
18 group member that had a lot of questions,
19 concerns and rated things oftentimes
20 insufficient evidence. I will say that the
21 developers did really an admirable job of
22 responding to my questions and alleviating

1 many of my concerns. So when you see those
2 values and I'm the left side outlier I would
3 modify a lot of my conclusions now based off
4 of feeling more comfortable with the models.

5 CO-CHAIR KNOWLTON: Salina?

6 MEMBER WADDY: So I was just
7 wondering regarding the transfer issue -- yes,
8 I'm back to that -- have they looked at if a
9 patient is at hospital A and then is
10 transferred to hospital B then it was that
11 hospital's decision to transfer, or that
12 physician or whatever, decision to transfer
13 the patient. So can whatever happened to the
14 hospital -- to the patient in hospital B
15 actually be attached to hospital A? And
16 whether or not that changes any of the
17 appearance of the mortality at the hospital.

18 CO-CHAIR KNOWLTON: Dr. Romano?

19 MEMBER WADDY: Does that make
20 sense?

21 DR. ROMANO: Yes, that is -- that
22 is potentially possible with linked data sets.

1 And I think you'll hear shortly about the CMS
2 measure that does precisely that.

3 It's not -- obviously the
4 practical problem is that many users who are
5 interested in looking at stroke mortality
6 don't have access to linked data across
7 hospitals. So we offer an alternative measure
8 that's based on the hospital's own outcomes.
9 But it is theoretically possible and it is
10 done with the CMS measure.

11 CO-CHAIR KNOWLTON: Greg?

12 MEMBER KAPINOS: I just wanted to
13 make a comment on -- I think it's about
14 usability.

15 CO-CHAIR KNOWLTON: Lean into your
16 mike. It's hard to hear you.

17 MEMBER KAPINOS: Sorry. So, I
18 wanted to make a comment and I hope it's under
19 this section of usability but earlier on when
20 we were discussing about the fact that it's
21 been implemented for 4 years and there's no
22 proof of misuse. Then Dr. Tirschwell asked

1 well, what is the proof that it's actually
2 used in a good way. I would -- then somebody
3 also said something about the fact that while
4 there's no -- there's no misuse and we can
5 look into subcategories of -- or like linkage
6 between mortality and other things. So it's
7 going to be useful to have this measure.

8 I want to say that maybe in 2008
9 we were not that close from the government
10 actually using those measures to make really
11 like big decisions on how much money will get
12 to each hospital as opposed to now we are I
13 think very much closer. So there could be a
14 misuse in the very near future about a
15 mortality measure that is actually not valid
16 and not capturing actually good quality of
17 care.

18 And number two, I wanted to say is
19 it not okay to not endorse one measure here?
20 We're not throwing all the work of the AHRQ in
21 the trash can, right? If it's not endorsed by
22 NQF we still can collect that -- I mean, that

1 Agency will still collect that data and
2 whoever is interested in actually using that
3 model to calculate what should be their stroke
4 mortality can still use that data.

5 So I'm just saying that my
6 understanding is that NQF measures will be
7 potentially used by the government as a
8 standard and dinging hospitals that don't do
9 a good job in terms of mortality. And I see
10 an issue with that. And I'm just saying that
11 maybe actually we can feel better about not
12 endorsing some measures because actually
13 there's also other agencies like the Joint
14 Commission and AHRQ that will continue to do
15 their job with those measures. Or am I wrong?

16 CO-CHAIR KNOWLTON: I wouldn't say
17 that you're wrong but I wouldn't want to
18 minimize the impact of NQF endorsement in
19 terms of what the government accepts, what CMS
20 accepts, what payers accept. It has great
21 sway in terms of what happens. This is a
22 consensus organization that has pretty deep

1 imprimaturs. So on the one hand what you say
2 is true. On the other hand I wouldn't want to
3 minimize the effect and be casual about it and
4 say oh well, they can do it anyway because it
5 has some real impact in the real world.

6 Other comments on this or are we
7 ready for a vote? Therese, you all set? Oh,
8 I'm sorry, Dr. Romano, you had another
9 comment.

10 DR. ROMANO: Well, I just want to
11 be clear and NQF staff can add to this maybe,
12 but I think that this process is really about
13 measures that can be used for transparency and
14 accountability. There's really a separate
15 process for measures that would be used for
16 payment which has to do with what's called the
17 Measure Applications Partnership. So, this
18 endorsement I don't think implies that the
19 measure would actually be used for hospital
20 payment which is a very specific pay-for-
21 performance application. So, just to be clear
22 about.

1 DR. BURSTIN: So, NQF endorsement
2 implies the measure is acceptable for a wide
3 range of accountability applications, from
4 certification all the way through. So again,
5 the Measures Application Partnership which
6 Patrick's referring to will make
7 recommendations on specific measures to be
8 used for specific programs, but that, you
9 know, again the assumption should be these
10 measures would be ready for all accountability
11 applications.

12 CO-CHAIR KNOWLTON: Right. Yes,
13 Dan, go ahead.

14 MEMBER LABOVITZ: I think this is
15 a measure which if publicly reported is
16 immediately understandable to the public.
17 Everybody gets death. But this is not a
18 measure that's able to account for stroke
19 severity. There is no way to grasp at that.
20 It doesn't really account for hospital
21 practices as far as comfort measures, end of
22 life care, transferring patients out.

1 I'm not satisfied that I really
2 heard enough about how it handles a hospital's
3 choice to accept patients coming in or choice
4 to send them out. That is -- I think Michael
5 Kaplitt's point on that is well taken. It's
6 going to get lost in the model in some --
7 because it's a relatively small number of
8 patients in a large cohort, but it may be
9 really driving your death statistic. I'm just
10 not sure that it -- I worry that some of our
11 tests for significance here, say an
12 interaction term, are way, way too stringent.

13 In the end there's a lot of
14 difficult decision-making and a lot of aspects
15 to these models which we don't completely
16 grasp. But in the end what everybody gets is
17 it's about death, and one hospital is going to
18 come out ahead of another hospital. If we
19 don't know really clearly what we're doing
20 with this I think we could take very good
21 hospitals and hurt them.

22 CO-CHAIR KNOWLTON: Gail?

1 MEMBER COONEY: Well, as a
2 consumer I just went on the Florida website
3 and pulled up the mortality data that appears
4 to be from this measure because it's using the
5 3M software. And the one hospital with the
6 higher than expected death rate is our Safety
7 Net hospital and they define higher than
8 expected as more deaths than expected given
9 how sick patients were. Just -- that's what
10 one consumer was able to pull off the website.

11 CO-CHAIR KNOWLTON: Anybody else?
12 Risha?

13 MEMBER GIDWANI: I'd just like to
14 hear those C statistics for the models when
15 they were disaggregated.

16 (Laughter)

17 MEMBER GIDWANI: I'm just -- were
18 we able to get that?

19 MR. GEPPERT: I did find them.
20 They were actually much better than I
21 remembered. So the disaggregated, they were
22 0.88 and 0.87 when they were disaggregated.

1 MEMBER GIDWANI: Okay, quite good.
2 Thank you.

3 DR. ROMANO: Just to clarify. So
4 again, those are disaggregated for ischemic
5 and hemorrhagic strokes separately. And those
6 are as good or better than C statistics that
7 have been generated using Get With the
8 Guidelines or clinical registry data. And I
9 think that reflects the fact that we do have
10 proxy measures of stroke severity in the model
11 such as patients who present comatose,
12 patients who present in a persistent
13 vegetative state, patients who present
14 seizing, and so forth.

15 MEMBER GIDWANI: Yes, those are
16 actually quite good values for discriminating
17 mortality.

18 CO-CHAIR KNOWLTON: Other
19 comments? Questions? Michael?

20 MEMBER KAPLITT: Yes, I agree. I
21 mean I think after having raised this point a
22 lot I would concede the point that you know,

1 while the transfer issue is an important one
2 to me if the numbers, you know, based on
3 stroke type are that relatively well
4 substantiated then presumably it's at least an
5 indirect reflection of you know, more
6 hemorrhagic strokes are going to be
7 transferred from one hospital to another. And
8 so if the numbers are, you know, sort of -- if
9 the numbers based on stroke type are, you
10 know, I mean I'll leave it to the
11 statisticians more to judge that. But you
12 know, I could concede the point that it's at
13 least at some level of, you know,
14 normalization.

15 CO-CHAIR KNOWLTON: Risha?

16 MEMBER GIDWANI: I don't think
17 that I handles the issue of transfer out that
18 you brought up, but in terms of transfer in I
19 wonder if the admit risk of mortality would
20 cover that.

21 MEMBER KAPLITT: Yes, that's what
22 I'm conceding. I mean I think that that's

1 fine. So I think that, you know, on the down
2 side it protects the hospitals that are taking
3 the sicker patients in transfer. I still
4 think it may artificially inflate the
5 hospitals that are doing less. But you know,
6 I concede most of that point.

7 CO-CHAIR KNOWLTON: Anything else?
8 Ready for a vote on usability. Let's vote.

9 MS. THEBERGE: Three high, nine
10 moderate, eight low, two insufficient.

11 CO-CHAIR KNOWLTON: Okay. It's a
12 close measure. We're moving onto feasibility.

13 MEMBER RICHMOND: Feasibility.
14 Our group had two high and one low. All data
15 are available in the electronic health record.
16 It uses administrative data.

17 CO-CHAIR KNOWLTON: Questions?
18 Comments? Seeing none let's vote on it.

19 MS. THEBERGE: Fourteen high, six
20 moderate, two low.

21 CO-CHAIR KNOWLTON: Okay.

22 MEMBER RICHMOND: So endorsement,

1 our group originally unanimously said no. We
2 had three nos. I can't speak for our group.
3 I'm very satisfied with the information that
4 we got from the developer. It answered a lot
5 of questions that I had and I spent an
6 inordinate amount of time with this measure.
7 So I have converted myself to yes on this.

8 CO-CHAIR KNOWLTON: Risha?

9 MEMBER GIDWANI: I'll say the same
10 thing. My "no" was really based off of
11 insufficient information. The developer
12 adequately answered my questions and I feel
13 comfortable so I would now in light of the new
14 information change my response to yes.

15 CO-CHAIR KNOWLTON: Other
16 comments? Thoughts? Okay, let's vote.

17 MS. THEBERGE: Fifteen yes, seven
18 no.

19 CO-CHAIR KNOWLTON: Well done,
20 progressed well through a relatively complex
21 questioning. We move on.

22 CO-CHAIR TIRSCHWELL: All right,

1 the next measure. Risha, can you take us
2 through 2026? Okay, sorry. I'm told that we
3 should give the developer a couple of minutes
4 to introduce the measure. Go ahead and start
5 anytime you're ready.

6 DR. BERNHEIM: Hi, this is
7 Susannah Bernheim. I am a physician and
8 researcher at Yale Center for Outcomes
9 Research and Evaluation, and we work --
10 louder? Sorry, okay. And we are working
11 under a contract with CMS and we're bringing
12 forward two measures today. I think we're
13 talking about our risk-standardized 30-day
14 mortality measure first. And I'm here with
15 Lein Han from CMS, Jeph Herrin who's one of
16 our statisticians, Judy Lichtman who is a
17 stroke epidemiologist and Elizabeth Drye who
18 will join us shortly.

19 I'm going to say just a couple of
20 very quick words about the measure itself and
21 then a few words about -- you still can't hear
22 me. I apologize. Okay. Better? A couple of

1 quick words about the measure itself and then
2 just one minute on risk adjustment for these
3 measures.

4 So this is a risk-standardized
5 measure. It is a 30-day mortality measure.
6 It evaluates mortality, all-cause mortality
7 following ischemic stroke at the hospital
8 level.

9 We -- for risk adjustment we are
10 using claims data and we are able to assess
11 patient risk looking both at the inpatient
12 claims and all of the inpatient and outpatient
13 claims for the 12 months prior. So we have
14 historical data on each of the patients.

15 The model uses a hierarchical
16 modeling that allows us to account for case
17 mix and clustering. And Karen spent nice time
18 this morning talking about that so I'm not
19 going to spend a lot of time on that.

20 Our measure considers transfers of
21 care as a contiguous hospitalization. We --
22 okay, sorry. Sorry, okay. Better, okay. For

1 patients who are transferred between one
2 hospital and the other. The hospital where
3 the patient is admitted is considered
4 accountable for that patient's mortality
5 outcome.

6 However, in consultation with an
7 amazing set of neurologists who consulted with
8 us on this measure we looked very carefully at
9 patients were seen only outside ED prior to
10 being admitted to the hospital. And based on
11 those evaluations we have added a risk
12 adjustment variable that assesses whether a
13 patient was transferred from an outside ED and
14 that is now risk adjusted for in this measure.

15 I want to take just one minute to
16 talk about claims data and explain what this
17 measure is meant to do and why the claims are
18 adequate to that task. The measure as you
19 know is designed to profile hospitals. So
20 conceptually we are trying to understand the
21 quality of care through the lens of patient
22 outcomes. And to do that we need to consider

1 those outcomes in the context of the patients
2 that come into the hospital.

3 What we are not trying to do is
4 build a prognostic tool for individual patient
5 outcomes. And this is a really important
6 differentiation and I just want to take one
7 minute on it. To predict an individual
8 patient outcome is a different task. We are
9 aiming to adequately assess the risk of the
10 full group of patients that come into a
11 hospital in order to have sufficient
12 confidence that the remaining variation that
13 we see is attributable to quality after we
14 account for uncertainty.

15 And what we have learned over time
16 is that the administrative data can do that
17 well. What you need to do this well is
18 variables that are consistently collected on
19 all of the patients. And we have the benefit
20 in fact of also having information that's
21 historical on these patients. And which
22 allows us to prevent some gaming.

1 Whereas a particular variable
2 might be critical for individual patient
3 prognostication, it may fail to be a good risk
4 adjustment variable for hospital profiling.
5 We've learned in this measure and others that
6 the administrative data can produce results
7 that are very close to what is achieved with
8 a model that uses medical record data.

9 And we've learned that by this
10 measure building the best administrative model
11 we can and then comparing the results at the
12 hospital level with the model that's been
13 built with medical record data. So not only
14 does our administrative claims model achieve
15 a C statistic that's quite comparable to
16 medical record models, but most importantly
17 it's not really in this case about perfect
18 patient prediction, it's about whether you're
19 assessing the hospitals correctly. And we can
20 do that by validating with a medical record
21 model. So we had the advantage of having a
22 national medical record model that we could

1 compare the results of our model with to be
2 sure that we were determining the same
3 information about a hospital as we would with
4 chart data. So I think that's a really
5 important concept that I just wanted to lay
6 out at the beginning.

7 As people know, there is wonderful
8 literature coming out of the stroke community
9 indicating the usefulness of the National
10 Institute of Health Stroke Scale for patient
11 prognostication. But sadly we're very far
12 away from having national reliably collected
13 data here. And so our task is to determine
14 whether we can do it well enough with
15 administrative claims.

16 And we're quite confident that
17 we're bringing forward a model that has a
18 level of patient discrimination that equals
19 many chart models and has a very strong
20 correlation with a medical record model.

21 MEMBER GIDWANI: Okay, thank you.
22 All right, so to start the panel discussion

1 I'll give a brief overview. Can everyone hear
2 me? Yes? Okay.

3 This is a 30-day all-cause
4 mortality rate following an acute ischemic
5 stroke hospitalization. The measure applies
6 to patients who are 65 years and older, and
7 mortality is defined as death from any cause
8 within 30 days of the admission that had the
9 principal diagnosis of acute ischemic stroke.

10 This measure and the risk
11 adjustment method was based completely off of
12 billing data, ICD-9 codes. It has a number of
13 exclusions from the denominator. Patients who
14 are transferred from another acute care
15 hospital will not be included in this
16 denominator. Patients who have inconsistent
17 or unknown mortality status or other
18 unreliable data, folks who were discharged
19 alive and against medical advice, and patients
20 who were enrolled in the Medicare hospice
21 program at any time in the 12 months prior to
22 being admitted for acute ischemic stroke are

1 also excluded from this measure.

2 This is an outcomes measure and
3 the predictor variables and the covariates
4 that are used in the risk adjustment are all
5 patient-level factors. The risk adjustment
6 method is a hierarchical logistical regression
7 model. The hierarchical component of that
8 allows the -- to account for the fact that
9 there are some similarities in patients that
10 are within the same hospital. There's going
11 to be clustering of observations and so the
12 hierarchical component models that aspect.

13 We had quite a lot of discussion
14 within our work group about this measure.
15 There were four work group members, three of
16 whom voted. In terms of the impact all three
17 work group members rated this as high.

18 CO-CHAIR TIRSCHWELL: Any comments
19 or questions about impact? Let's go ahead and
20 vote on impact. Go ahead and vote now.

21 MS. THEBERGE: Twenty-one high,
22 one moderate.

1 CO-CHAIR TIRSCHWELL: Okay. Why
2 don't we move onto 1c which is evidence as is
3 relevant.

4 MEMBER GIDWANI: Okay. This is a
5 health outcome measure.

6 CO-CHAIR TIRSCHWELL: I don't know
7 that we need to go into any further detail.
8 Any comments or questions about that? Let's
9 go ahead and activate the voting. Go ahead
10 and vote.

11 MS. THEBERGE: Twenty-two yes.

12 CO-CHAIR TIRSCHWELL: Great. And
13 then onto 1b which is evidence of a gap.

14 MEMBER GIDWANI: In terms of
15 evidence of a performance gap the developers
16 presented information on deaths by age,
17 gender, race, ethnicity and SES. They show
18 that there is -- that the rate of adverse
19 outcomes and complications associated with
20 stroke increases with advanced age. They note
21 that the overall death rate for stroke is
22 higher amongst black patients compared with

1 whites. They note that the stroke incidence
2 rate is higher for men compared with women at
3 younger ages but not at older ages.

4 And in terms of SES they did not
5 see a risk-standardized mortality rate
6 difference across SES quintiles of hospitals.
7 The data that they are showing on disparities
8 by population group are about the outcome of
9 mortality rather than the difference between
10 observed to expected mortalities so I'd like
11 to point that out.

12 With respect to the work group
13 evaluation, let's see. For performance gap
14 all three members voted to rate this as high.

15 CO-CHAIR TIRSCHWELL: Any other
16 questions or comments about performance gap?
17 Let's open up the voting then. Go ahead and
18 vote now.

19 MS. THEBERGE: Twenty high, two
20 moderate.

21 CO-CHAIR TIRSCHWELL: So then
22 scientific acceptability, reliability first.

1 MEMBER GIDWANI: With respect to
2 the reliability two work group members rated
3 this as medium, one group member rated this as
4 low.

5 If I can make a comment here, the
6 developer showed reliability statistics
7 showing the agreement between the risk-
8 standardized mortality ratio for each
9 hospital. The administrative data set was 0.4
10 which is considered moderate.

11 CO-CHAIR TIRSCHWELL: Any other
12 comments or questions about reliability?
13 Let's go ahead and open the voting.

14 MS. THEBERGE: Three high,
15 eighteen moderate, one low.

16 CO-CHAIR TIRSCHWELL: Okay, next
17 is validity.

18 MEMBER GIDWANI: There was quite a
19 conversation regarding validity and this is
20 where really the crux of most of the
21 conversations and the questions the developer
22 were posed.

1 The work group rated -- we had
2 three scores. Two folks rated this as having
3 insufficient evidence. One person rated this
4 as having high evidence of validity.

5 CO-CHAIR TIRSCHWELL: Okay. I'll
6 start with a question for the developer. You
7 said that specifically you have some patient
8 chart-abstracted data that you used as sort of
9 a gold standard to compare your assessment to.
10 So the hospital ratings which are sort of
11 where the rubber hits the road on this whole
12 thing were highly correlated, sort of the
13 order of rating was correlated between the
14 model and the one based on the theoretical
15 gold standard based on chart review? Could
16 you respond?

17 DR. BERNHEIM: Right, that's
18 right. We did that validation and the
19 correlation between the chart model output for
20 each hospital and the administrative was 0.8.

21 CO-CHAIR TIRSCHWELL: So that's
22 the chart model output using the same

1 specification or you used additional patient-
2 level detail like NIH Stroke Scale score too?

3 DR. BERNHEIM: Right. So the way
4 we develop the chart model is de novo
5 essentially. We take the variables that are
6 available in the chart model and create a new
7 risk adjustment model using medical record
8 data.

9 And so then we profile hospitals
10 based on the medical record data-based model
11 and the administrative-based model, and we
12 look at how closely the results of that model
13 for each hospital are correlated. And so
14 we're learning the same information about each
15 hospital, well, to a 0.8 based on one model
16 and the other. I'm confusing you, I can see -
17 -

18 CO-CHAIR TIRSCHWELL: So you're
19 just correlating the predicted mortality
20 between one model and the other?

21 DR. BERNHEIM: Correlating the
22 risk-standardized mortality rate between the

1 two models.

2 CO-CHAIR TIRSCHWELL: How's about
3 comparing the ratings of the hospital? You
4 line up all your hospitals from Connecticut --

5 DR. BERNHEIM: The same thing.
6 That's what we're doing essentially.

7 CO-CHAIR TIRSCHWELL: So what's
8 the correlation?

9 DR. BERNHEIM: 0.8.

10 CO-CHAIR TIRSCHWELL: That's the r
11 or the r-squared?

12 DR. BERNHEIM: That's the r -- r-
13 squared.

14 CO-CHAIR TIRSCHWELL: 0.8 is the
15 r-squared? That would mean that your r was
16 0.9 which is fantastic.

17 DR. BERNHEIM: You can see -- it's
18 in our technical report. You can see it
19 listed with the correlation coefficient of
20 0.8.

21 CO-CHAIR TIRSCHWELL: Okay.

22 DR. BERNHEIM: It was the r. I

1 was correct the first time.

2 CO-CHAIR TIRSCHWELL: Any other
3 questions that people have about that? I have
4 another question about validity for the
5 developers.

6 So you know, looking at your list
7 of variables that sort of stay in your model
8 which is extensive, you know, in your
9 introduction you talk about conditions present
10 on admission. So -- and I don't see any real
11 clinical adjusters. So you know, it was
12 previous 12 months plus the index admission.
13 But again, I'm sure that you were careful not
14 to, you know, include anything that might be
15 an indication of poor quality care. And I
16 don't see anything like coma or anything that
17 might be a marker of severity. So can you
18 comment on whether those things were tried and
19 they just didn't stay in the model?

20 DR. BERNHEIM: I think there's two
21 questions embedded in there so I'm going to
22 take one at a time.

1 So yes, we're very careful that
2 the risk adjusters that are used from the
3 index admission don't include complications of
4 care. At the time this model was developed
5 POA indicators were not adequate to that task
6 so what we do is we create a list of risk
7 adjustment variables that if they are only
8 present during the index stay may represent a
9 complication and we do not risk-adjust for
10 them unless they are also present
11 historically.

12 So if a patient has a history of
13 renal failure we would adjust for it if they
14 only appear to have had it during the index
15 admission. We would not use that as a risk
16 adjuster. That's how we handle the
17 complications issue.

18 I think your second question was
19 where are things like coma. So, the
20 administrative claims do not have a stroke
21 severity scale. There are some indicators.
22 We use a condition grouper that is a CMS

1 condition grouper, and so some of these
2 individual variables you can't see. A few of
3 them are embedded in there, but again going
4 back to my earlier remarks, what we find is
5 even without those indicators when you
6 aggregate at the hospital level we get an
7 adequate sense of the risk of those patients
8 coming into the hospital.

9 CO-CHAIR TIRSCHWELL: Okay. And
10 then one final thing about the -- there's a
11 large number of comorbid medical conditions
12 which seem to be paradoxically protective
13 against a prediction of death. And I guess I
14 don't understand how they stand up to the face
15 validity criteria.

16 DR. BERNHEIM: Yes, this is
17 something that often confuses people and we've
18 spent some time thinking about it. So
19 hypertension is a classic example here that
20 confuses people.

21 What you need to remember is that
22 we're looking at not just a blood pressure

1 value as a patient walks in the door with a
2 stroke but historical data. And you'll find
3 even in chart models that if you're looking at
4 this this way the hypertension often is a
5 marker of sort of being less severely sick
6 because it's what's managing to get coded and
7 that's how we interpret that. And we see that
8 a lot. I mean, in the aggregate again these
9 risk adjusters work very well, but some of
10 them because they are historical chart data
11 can seem somewhat paradoxical.

12 CO-CHAIR TIRSCHWELL: I guess it
13 still doesn't quite seem to meet the face
14 validity criteria. It just suggests that it
15 adds power to your prediction. It doesn't --
16 I just --

17 MEMBER J. BAUTISTA: I think what
18 she's saying is that the patient saw a doctor
19 and got diagnosed with hypertension and so is
20 actually being treated. And that's --

21 CO-CHAIR TIRSCHWELL: I get what
22 she --

1 MEMBER GIDWANI: I sort of didn't
2 really understand the response to the first
3 question. So you're saying that -- what
4 happens if a patient comes to a hospital and
5 they're a transfer patient and we don't have
6 a history on them because our hospital is in
7 California and those patients live in Arizona.

8 CO-CHAIR TIRSCHWELL: These are
9 Medicare data. It's national. It's all
10 together.

11 MEMBER GIDWANI: Okay, all right.
12 Okay, fair enough.

13 So, I'm also hoping we can bring
14 up Table 9 on page 30 of the Methods Report so
15 that everybody can get a chance to look at the
16 coefficients and really to go off of what
17 David brought up of some of these
18 paradoxically protective conditions.

19 And I also didn't understand in
20 terms of let's say coma or cerebral edema,
21 mass effect, altered consciousness, those
22 weren't variables that were included in your

1 model. Were they not originally included in
2 consideration, or were they considered and
3 then dropped out of the model because they
4 weren't statistically significant?

5 DR. BERNHEIM: So, I think you're
6 bringing up the table there. So essentially
7 every ICD-9 condition code is considered. We
8 use a grouper that collects them into CCs.
9 Sometimes that makes it hard to see individual
10 ICD-9 codes that you're looking for.

11 We categorically exclude some that
12 aren't relevant to Medicare patients like
13 pregnancy, but otherwise all however many
14 thousand ICD-9 codes are considered as
15 candidate variables. And then you see they
16 each are listed as a CC. So some of these
17 things you're looking for are going to be
18 embedded in other CCs. We have some that have
19 to do with disability such as hemiplegia.

20 But again, I think the more
21 important piece here is that this is very
22 different than a chart model. We're not using

1 just a few key variables that are showing up
2 in a chart when they're arriving.

3 MEMBER GIDWANI: But what this is
4 showing then is that something like cerebral
5 edema is not having a role to play in
6 predicted mortality, but history of infection
7 or major psychiatric disorders is contributing
8 to the risk of mortality.

9 DR. BERNHEIM: Though I suspect
10 the cerebral edema is embedded in one of
11 these. We could find out, right? I mean
12 again these are grouped variables.

13 MEMBER GIDWANI: Okay.

14 DR. BERNHEIM: Each of these CCs
15 represents tens to hundreds of ICD-9 codes.

16 MEMBER GIDWANI: Okay. And then
17 also in terms of cerebrovascular and
18 cardiovascular this is saying that aneurysm is
19 protective against mortality, that circulatory
20 defects or congenital cardiac defects are
21 protective against mortality. So I too am
22 having a hard time with the face validity of

1 this.

2 DR. BERNHEIM: There are certain
3 things that get forced into the model because
4 the clinical experts that we worked with felt
5 that they were important to include in the
6 model. So you're see some of the ones you're
7 pointing to there the confidence interval is
8 crossing 1 and so they don't all actually come
9 out as statistically significant.

10 I would say this is one of the
11 pieces of our model that committees typically
12 struggle with and it is I think probably where
13 we were 8 years ago. What we have learned in
14 that time is that in aggregate these models do
15 a very good job of assessing the risk of the
16 patients that are coming in. They stand up
17 against chart models in case after case.

18 And now we are having the benefit
19 of doing more study and learning from some of
20 our measures that have been in play for longer
21 that when you go into the hospitals that do
22 well in these models you see different

1 characteristics. And we haven't had a chance
2 to do that with stroke yet but we have done in
3 other conditions.

4 MEMBER GIDWANI: So one thing I'd
5 also like to point out is that correlation
6 between an administrative-based model and
7 chart review may be very high, but if those
8 models are both doing a poor job of predicting
9 they can still have poor predictive ability
10 and high correlation. So, they're just --
11 would then be doing an equally poor job of
12 predicting.

13 In this case the ROC statistic,
14 the C statistic or the area under the ROC
15 curve is I believe 0.80 which is reasonable.
16 It's not great but it's certainly reasonable.
17 To put that in perspective a C statistic of
18 0.5 would mean that the model has no
19 discriminative ability.

20 DR. BERNHEIM: Can I make one
21 quick comment on the C statistic issue?

22 CO-CHAIR TIRSCHWELL: Yes, go

1 ahead.

2 DR. BERNHEIM: Again, we've talked
3 a little bit about why it's not the only thing
4 that matters in this model. But I also would
5 caution the committee that high, high C
6 statistics can mean that you're really
7 absorbing a lot of the hospital's impact,
8 right?

9 I mean, we suspect that a
10 patient's outcome is related partly to the
11 risk that they bring into the hospital and
12 partly to the care they give. And that's why
13 it's really important that we do not risk-
14 adjust for those things that may be
15 complications of care. We lose in that case
16 our ability to understand the hospital's
17 impact on a patient. And so a high C
18 statistic does not always mean that the model
19 is better performing. It can easily mean that
20 the model is essentially absorbing that which
21 you're most looking for. So you need to have
22 some caution in this.

1 The chart models are often in the
2 0.7 to 0.8 range, the ones that are published.
3 So you know, both our administrative model and
4 our chart model are right in that standard
5 range.

6 CO-CHAIR TIRSCHWELL: Anything
7 else? Yes, go ahead, Karen.

8 DR. PACE: I just wanted -- I
9 didn't bring this up when we were going
10 through my initial slides, but just in terms
11 of performance metrics and risk models, to
12 keep in mind that for risk models we're
13 purposely only including patient factors
14 present at the start of care. So, you are
15 going to have different benchmarks on these
16 model performance compared to, say, a total
17 explanatory model where you might be including
18 the care provided and elements of quality of
19 care. So just to kind of keep that in
20 perspective of, you know, we're only including
21 those patient characteristics in risk models.

22 CO-CHAIR TIRSCHWELL: Any other

1 comments? Greg, go ahead.

2 MEMBER KAPINOS: I just wanted to
3 make a comment about like when you were
4 talking about cerebral edema and coma. So,
5 those are abstracted from the billing, right?
6 Not from the coding of the complete notes.
7 And because ischemic strokes are pretty
8 severe, usually taken care by the ER
9 physician, then maybe a neurointensivist, a
10 neurosurgeon, a neurologist, a vascular
11 neurologist. And some systems of billing are
12 limited to four ICD-9 codes that you can bill
13 for. I am familiar with many intensivists
14 actually restricting the number of codes that
15 they use so that actually the other team can
16 also bill for the same patient. And it's not
17 uncommon to have, as I said, three or four
18 physicians billing on the same day for the
19 same ischemic stroke patient.

20 So very often then in my practice
21 I have not coded a lot of cerebral edemas and
22 comas because they were already with an

1 ischemic stroke and a respiratory failure.

2 And my system does not allow me to bill for
3 more than four codes.

4 So I just want to hear back, I
5 mean hear like what's the validity of like
6 abstracting the severity of the patients from
7 ICD-9 codes on the billing system as opposed
8 to just the notes. And even if we use the
9 notes with the DRG and all those fancy models
10 to try to capture the severity of the patient
11 it has -- many clinicians complain that it is
12 still also very imperfect because actually the
13 way you -- whether you dictate your notes or
14 a lot of people are just handwriting or typing
15 does not translate really well. There's
16 sometimes like if you say "pulm edema" instead
17 of "pulmonary edema" that's not going to be
18 charted -- that's not going to be coded for
19 your patient. So there's a lot of -- there's
20 a lot of things that make the system of DRG or
21 billing with the ICD-9 code extremely
22 imperfect.

1 And from -- I'm junior, so I
2 cannot really -- I want to hear from other,
3 more senior clinicians to confirm that there
4 is actually some good degree of validity to
5 use those billing or DRG system to capture the
6 severity of our patients. Because my
7 understanding is that it's extremely imperfect
8 and so therefore there would be no validity in
9 those models that we're talking about.

10 CO-CHAIR KNOWLTON: Jolynn, do you
11 want to respond?

12 MEMBER SUKO: I think we're
13 getting confused. These are based on facility
14 codes. So these are the bill that your
15 hospital submits for the nursing care, all of
16 the other care. And that's typically done in
17 a centralized fashion by coders.

18 I would agree with you that
19 probably on the physician side when you think
20 about the variation of practice, some
21 physicians are employed, some physicians are
22 in private practice. It's going to be

1 different. But these are not based upon the
2 codes that you -- they are based upon your
3 documentation but they're not based upon the
4 codes that you as physicians submit on your
5 Part B billing slips.

6 CO-CHAIR TIRSCHWELL: Although, I
7 mean for the acute care admission I think
8 that's true but there's all this outpatient
9 data from the previous 12 months which are
10 more related to physicians.

11 MEMBER SUKO: Right.

12 CO-CHAIR TIRSCHWELL: Gail?

13 MEMBER COONEY: I just have a
14 question about the exclusion of the Medicare
15 hospice patients and why. Well, my first
16 question started to be why it was only an
17 exclusion on day one, but now I understand
18 that that's because that's all we're looking
19 at. But why is that not a measure of frailty
20 that you would want included in your model?

21 DR. BERNHEIM: I just want to make
22 sure I understand your question. Why do we

1 not risk-adjust for hospice as opposed to
2 exclusion?

3 MEMBER COONEY: To exclusion, yes.

4 DR. BERNHEIM: It's an interesting
5 question. I think the feeling of the clinical
6 experts was that as opposed to being a frailty
7 marker it was really a marker that in these
8 patients a mortality outcome was not an
9 appropriate measure of quality.

10 CO-CHAIR TIRSCHWELL: High
11 mortality was almost inevitable probably.

12 DR. DRYE: Hi, Elizabeth Drye from
13 Yale. Another way to think about it is that
14 this outcome measure is judging hospitals
15 based on, you know, whether their patients
16 live or die. And when we have a patient
17 already enrolled in hospice when they're
18 admitted, then it's clearer that their goal is
19 not necessarily survival. So that's why we
20 don't put them in the measure there. But a
21 different goal instead of risk-adjusting for
22 them.

1 CO-CHAIR TIRSCHWELL: Risha?

2 MEMBER GIDWANI: First off my
3 question is -- one of my questions is these
4 estimates, are these log odds that are being
5 presented? These coefficients.

6 DR. BERNHEIM: The fourth column
7 there, yes.

8 MEMBER GIDWANI: No, the estimate.

9 DR. BERNHEIM: Right, the fourth
10 column is the odds ratio. The --

11 CO-CHAIR TIRSCHWELL: First column
12 is the --

13 DR. BERNHEIM: The first column is
14 log odds, right. And the standardized
15 estimate is the standardized estimate.

16 MEMBER GIDWANI: Okay. Again, I'm
17 going to make the suggestion that all data
18 that are presented for coefficients in the
19 future be presented as probabilities. Even
20 odds ratios can be difficult to understand.

21 More so than that though I have
22 actually a few comments and questions. One,

1 I'm going to bring up again this issue of
2 where patients are discharged or where they're
3 coming in from. That's not accounted for in
4 these models. If there's a higher risk of 30-
5 day mortality from somebody who's been Life
6 Flighted in that's not going to be taken into
7 account here. If there's a higher risk of
8 mortality for patients who were discharged to
9 a nursing home versus to their home that
10 wouldn't be taken into account here.

11 I understand the limitations of
12 what you can use from billing and
13 administrative data but my larger concern
14 stems from the fact that CMS has moved to
15 value-based purchasing and that there is a
16 move towards CMS being instead of a fee-for-
17 service provider being a fee-for-value
18 provider and that mortalities and readmissions
19 are a part of their move and that there are
20 financial penalties as well as financial
21 benefits associated with having different
22 levels of mortality and readmissions compared

1 to the expected level of mortality and
2 readmissions. So I think it's really
3 important that we get these models right given
4 their potentially large implication in the
5 future.

6 CO-CHAIR TIRSCHWELL: You can
7 respond if you like.

8 DR. BERNHEIM: I'll just say two
9 quick things. We purposefully don't risk-
10 adjust for where a patient goes again on the
11 principle that that has something to do with
12 the care that's being provided and those
13 decisions reflect that quality. So to the
14 extent that we're not making the right
15 decisions about where to send people that
16 should be reflected in the differences among
17 the hospitals.

18 In terms of where patients are
19 coming from you're right, we can't do the
20 adjustment for a Life Flight, but again we did
21 with careful consideration and input from our
22 clinician group make sure that we were

1 adjusting for patients who are coming from an
2 outside ED which will handle some of that
3 issue.

4 As to the implementation question
5 my understanding, and NQF can speak to this
6 better, is that this is a measure that's been
7 designed for public reporting and this group
8 is here to evaluate its scientific
9 acceptability in that setting. But I would
10 leave that to NQF's guidance.

11 DR. PACE: I just wanted to
12 confirm, you know, the discharge -- where the
13 patients discharge to would be something
14 that's a factor after the start of care. So
15 risk models should include patient
16 characteristics at the start of care, not
17 things that happen during or at the end of
18 care.

19 So, and in terms of where we're at
20 now it's about the validity of the measure as
21 it was specified and documented. So, you
22 know, if you have specific questions about

1 that, you know, as Helen said earlier you
2 know, we have one set of criteria and we
3 expect measures to meet those criteria.

4 Obviously the Measure Application
5 Partnership does recommend measures that will
6 be used by CMS in a variety of programs
7 including the payment programs. But we do
8 need to focus on your questions about the
9 validity and, you know, obviously that relates
10 to what you're talking about.

11 CO-CHAIR TIRSCHWELL: Okay. Any
12 other comments on validity before we go to a
13 vote? Okay, let's go ahead and open up the
14 voting for validity.

15 MS. THEBERGE: Three high,
16 thirteen moderate, five low, one insufficient.

17 CO-CHAIR TIRSCHWELL: Okay.
18 Moving on next to usability.

19 MEMBER GIDWANI: With respect to
20 usability the work group was divided. There
21 was one person who rated this as high, one
22 person who rated this as medium, one person

1 who rated this as insufficient stating the
2 questions about validity need to be settled
3 before answering this question.

4 CO-CHAIR TIRSCHWELL: So, okay.
5 Sounds like -- and I don't know this for sure,
6 but perhaps after some of the answers that
7 were received the "insufficient" might not be
8 insufficient anymore. Any comments or
9 questions about usability?

10 Let's go ahead and open the voting
11 then about usability. One response short.
12 Could everybody just hit their button one more
13 time. There we go.

14 MS. THEBERGE: Four high, eighteen
15 moderate.

16 CO-CHAIR TIRSCHWELL: Okay.
17 Moving onto feasibility.

18 MEMBER GIDWANI: With respect to
19 feasibility these are all data based off of
20 the administrative billing record. There was
21 one person who rated this as high and two
22 people who rated this as medium.

1 One of the comments were that the
2 required data elements, i.e., mortality, do
3 not seem to be routinely gathered nor is there
4 a data collection strategy in place. Another
5 person said the measure is not in operational
6 use but all elements are part of the
7 electronic health record. I'll remind NQF
8 panel members that these are based off of ICD-
9 9 billing data.

10 CO-CHAIR TIRSCHWELL: Any
11 comments? Questions about feasibility?

12 DR. BERNHEIM: I can just comment.

13 CO-CHAIR TIRSCHWELL: Yes, go
14 ahead.

15 DR. BERNHEIM: Medicare is
16 extremely good at collecting mortality data
17 and that's been validated. So I think the
18 mortality concern for the Medicare population
19 is not a concern.

20 CO-CHAIR TIRSCHWELL: Okay, thank
21 you. Let's go ahead and open the voting.

22 MS. THEBERGE: Fourteen high,

1 eight moderate.

2 CO-CHAIR TIRSCHWELL: And then
3 finally overall suitability for endorsement.
4 Risha, any final comments?

5 MEMBER GIDWANI: There were two
6 people who voted no, one person who voted yes.

7 CO-CHAIR TIRSCHWELL: And again
8 that was before you got the substantial amount
9 of clarification?

10 MEMBER GIDWANI: That's correct.
11 One person said this is a preliminary
12 conclusion and another person said, "I would
13 like further information and discussion about
14 the presence or absence of stroke severity as
15 part of risk adjustment prior to supporting
16 endorsement."

17 CO-CHAIR TIRSCHWELL: And I think
18 we've heard about really all of those issues.
19 Any other comments or questions?

20 Let's go ahead and open the voting
21 then for overall suitability.

22 MS. THEBERGE: Eighteen yes, four

1 no.

2 CO-CHAIR TIRSCHWELL: Okay, thank
3 you. Sure. Okay. Everybody take a deep
4 breath and we'll move onto a very similar
5 measure in some ways, different in others,
6 2027: Hospital 30-day All-Cause Risk-
7 Standardized Readmission Rate Following Acute
8 Ischemic Stroke Hospitalization. Same group
9 developed it and Risha will again be
10 presenting.

11 MEMBER GIDWANI: Thank you. This
12 is measure 2027 submitted by CMS. The measure
13 looks at the hospital-level outcome of
14 readmission following an acute ischemic stroke
15 hospitalization for patients aged 65 or older.

16 The readmission rate is risk-
17 adjusted and is it also all-cause meaning that
18 any readmissions count, even those unrelated
19 to stroke.

20 The measure does exclude
21 admissions for patients who had an in-hospital
22 death. These patients are of course not

1 eligible to be readmitted. It also excludes
2 patients who are transferred to another acute
3 care facility. In that case if there were any
4 readmissions it would be attributed to the
5 second hospital that the patient was
6 transferred to.

7 It also excludes patients who were
8 discharged alive and against medical advice,
9 and excludes patients without at least 30 days
10 post-discharge claims data because they need
11 that amount of information to assess whether
12 the readmission occurred or not.

13 Again, the level of analysis is at
14 the facility level and this is based off of
15 administrative claims data.

16 CO-CHAIR TIRSCHWELL: so starting
17 with impact.

18 MEMBER GIDWANI: Yes, one second
19 please. In terms of the impact there were two
20 persons voting high, one person voting medium.

21 CO-CHAIR TIRSCHWELL: Any
22 questions or comments on impact? Okay, let's

1 go ahead and open the voting for impact. Two
2 short.

3 MS. THEBERGE: We are short two.

4 CO-CHAIR TIRSCHWELL: Oh, we
5 should only get 21. Oh, we're missing
6 somebody over there as well? Okay, so then
7 we're good.

8 MS. THEBERGE: Seventeen high,
9 three moderate.

10 CO-CHAIR TIRSCHWELL: Okay, moving
11 onto 1c. I guess this is an outcome measure
12 but I guess we still need to vote one way or
13 the other for evidence. Any questions or
14 comments about evidence?

15 Okay, let's go ahead and open the
16 voting. Oh yes, Greg. I can't hear you.

17 DR. PACE: We do consider it a
18 health outcome because it's really a proxy for
19 deterioration in health status. So, generally
20 we categorize readmission measures as health
21 outcome measures.

22 MEMBER KAPINOS: But the trigger

1 to be readmitted can be very low so there
2 could be no deterioration, just self -- I
3 mean, to me no, that's not really
4 deterioration. That's not absolutely the
5 direct measure of morbidity or mortality.
6 Therefore it's not a health outcome.

7 DR. PACE: That's why I said we
8 consider it a proxy, but we do classify it as
9 a health outcome requiring risk adjustment, et
10 cetera.

11 CO-CHAIR TIRSCHWELL: Let's
12 restart the voting for evidence. I think
13 that's it if there's still someone missing
14 down there.

15 MS. THEBERGE: Sixteen -- I'm
16 sorry, nineteen yes, two no.

17 CO-CHAIR TIRSCHWELL: And then
18 moving onto performance gap.

19 MEMBER GIDWANI: With respect to
20 the performance gap developers presented
21 information showing that there was a median
22 hospital readmission rate for stroke patients

1 across the country of 14 percent. They noted
2 there's a large variation in outcomes for
3 readmission with rates ranging from 10 percent
4 to about 19 percent, and those data represent
5 the 25th and 75th percentiles.

6 They also looked into disparities
7 by population group with population group
8 being defined as race or SES, noting though,
9 however, little work has actually been done on
10 these populations. With respect to race they
11 were not showing racial disparities for
12 African-American patients. With respect to
13 SES they looked at these disparities by
14 looking at the proportion of patients that
15 have dual eligible patients, meaning that they
16 are Medicare and Medicaid, and found that
17 compared to the national average hospitals
18 with higher proportions of dual eligible
19 patients did not have worse 30-day risk-
20 standardized readmission rates.

21 With respect to the work group
22 panel's -- the work group's evaluation of the

1 performance gap, two persons voted high, one
2 person voted medium.

3 CO-CHAIR TIRSCHWELL: Any other
4 comments or questions about performance gap?
5 Let's go ahead and open the voting. Go ahead
6 and vote now.

7 MS. THEBERGE: Fifteen high, seven
8 moderate.

9 CO-CHAIR TIRSCHWELL: Okay,
10 reliability.

11 MEMBER GIDWANI: For reliability
12 the work group members voted two medium, one
13 high.

14 CO-CHAIR TIRSCHWELL: Any
15 questions or comments about reliability?
16 Let's go ahead and open the voting and go
17 ahead and vote now. One vote short. There we
18 go.

19 MS. THEBERGE: Ten high, twelve
20 moderate.

21 CO-CHAIR TIRSCHWELL: Now,
22 validity.

1 MEMBER GIDWANI: Validity again is
2 where this work group had the most intensive
3 conversation with developers. There were
4 quite a lot of questions about the validity of
5 the measure as specified. One person voted
6 this to have medium validity. Two people
7 voted this to have insufficient validity.

8 There were a number of questions
9 that were posed by the work group members.
10 Developers did respond to many of those
11 questions. They also did refer us to a report
12 that was convened by CMS. They asked the
13 presidents of all statistical societies within
14 the United States to review their risk
15 adjustment models. I read that report. The
16 presidents did review these models and found
17 them to be appropriate with respect to
18 methodology. And that means that the
19 statistical approach is appropriate.

20 I do still have some questions
21 about the clinical aspects of the model. I'll
22 allow other people to ask their questions but

1 -- and I'll save mine until other folks have
2 a chance to speak.

3 CO-CHAIR TIRSCHWELL: Okay.
4 Michael?

5 MEMBER KAPLITT: So, with respect
6 to the clinical aspects let's talk about your
7 exclusion criteria for a second. Given the
8 intent of this particular measure, so why --
9 for example, why are not, you know, people who
10 are readmitted for completely irrelevant
11 reasons excluded? If somebody comes back
12 let's say 3 weeks later with a newly diagnosed
13 cancer. I know that sounds crazy but I'm just
14 trying to use, you know, an obvious example
15 that has nothing to do with their stroke
16 outcome.

17 And a corollary to that is also a
18 planned readmission. So for example, let's
19 say someone gets a hemicraniectomy because
20 they are swelling and you take off their bone
21 plate. I personally would wait 3 months but
22 some people if they do very well might want to

1 do it in let's say 3 weeks. We would
2 obviously want to encourage people to let
3 people leave the hospital and then come back
4 rather than encourage them to keep them in the
5 hospital for no good reason just so that their
6 statistics look better. So why were those
7 things not part of the exclusion?

8 DR. BERNHEIM: I'm going to take
9 them in reverse order because they're easier
10 that way.

11 The planned readmissions that you
12 point out are excluded. We should have made
13 that clear to the committee. So, we went
14 through with our clinical experts and
15 discussed any likely follow-on procedures that
16 would be scheduled as follow-on care, the
17 largest one being carotid endarterectomy
18 obviously. But we did include cranioplasty in
19 that. That list is on page 11 of our
20 technical report. And so those readmissions
21 are excluded as long as they are not
22 accompanied by a primary discharge diagnosis

1 that suggests that this was an acute
2 readmission. So if you come back with another
3 stroke then it would be included.

4 The question about cancer
5 diagnoses, or people's favorite example is car
6 crashes is a good one that we get a lot. And
7 it's -- we feel it's really important to look
8 at an all-cause unplanned readmission for a
9 couple of reasons.

10 One is that from the patient's
11 perspective this is what affects them. But
12 more importantly except in the very rare case
13 of the car crash it turns out to be really
14 impossible to differentiate what's been
15 related versus unrelated. You know, patients
16 come back septic and it may have been
17 something related to the line that they had in
18 the hospital. It may not have had anything to
19 do with it. And people have done a lot of
20 work with chart measures trying to see if you
21 can parse these things out and you can't.

22 The important question is is one

1 hospital likely to have a much higher rate of
2 these kind of random things, and we think that
3 that's really unlikely. We're not in any way
4 suggesting all readmissions are bad or that
5 readmission rates should be zero. We're
6 looking to see whether given the case mix you
7 have, you have a higher than expected rate of
8 readmissions. And in that case we think these
9 other issues pretty much fall out.

10 MEMBER KAPLITT: I think that's
11 probably true. It's something that I would
12 think should be testable, right? I mean
13 you're right, it should be a minority you
14 would think, although you could make an
15 argument that a level one trauma center which
16 is also a higher level of care for other
17 reasons might be disproportionately affected
18 by it. But I still agree that it's probably
19 an extreme minority but I would think you
20 should be able to generate that data to show
21 that it's a minority, right? That it's not
22 affecting your measure. You should be able to

1 get data on that point I would think.

2 DR. BERNHEIM: So, I'm not sure
3 exactly -- so we've worked with colleagues who
4 have done -- to try to do this at a chart
5 level. Are you suggesting with the
6 administrative claims model see how many come
7 in? I'm not totally sure how we would do that
8 exactly.

9 MEMBER KAPLITT: Well, I mean so
10 for example -- well, I mean, I don't want to
11 sit here and work it out with you because we
12 don't have the time for this. But you know,
13 you could do a prospective study where you
14 look at readmissions, right? For the same
15 patient in the same hospital looking at the
16 diagnoses, and then identify certain diagnoses
17 that might require more further, you know,
18 intensive chart review to be able to get a
19 sense of whether or not this is a serious
20 problem. I mean, I agree that it's probably
21 a minority so I don't want to waste an hour on
22 this, but.

1 DR. BERNHEIM: No, and there have
2 been some studies like that. And again, they
3 mostly indicate that it's a challenging task
4 to parse.

5 CO-CHAIR TIRSCHWELL: So I have a
6 question for the developers and it mostly
7 relates to the C statistic of 0.6. And I
8 guess, you know, in my simple perspective if
9 your C statistic is 0.5 then the information
10 that you're giving as the result of your model
11 would essentially be kind of random noise, if
12 it's 0.1 then you're speaking the truth and
13 everything else in between is a gradation.

14 At 0.6 it seems like there's a lot
15 of noise that must be coming out from the
16 results and given the amount of noise that
17 must be in there the fact that you're grading
18 hospitals based on this, that there's public
19 reporting that might influence patient
20 behavior. You know, I guess to me with a
21 model of 0.6 it's hard for me to justify using
22 that information which, you know, I don't want

1 to say -- "unreliable" isn't the right word
2 necessarily, but it just seems like how can I
3 really rely on that.

4 And certainly an end user consumer
5 without any appreciation of that sort of lack
6 of discrimination will only be looking at the
7 end result and they'll take it as gospel. And
8 so I really struggle with how this is really
9 valid for determining much at all.

10 DR. BERNHEIM: So I'm going to go
11 back to something I said earlier which is
12 remember that we're not attempting to predict
13 a patient's likelihood of readmission. We're
14 trying to understand what's happening at a
15 hospital level. So a 0.1 would mean this was
16 a useless measure because it would say that
17 there's no difference between hospitals.
18 Everything's explained by the patient
19 characteristics when they walk in the door,
20 right? So a 0.1 is not a helpful measure that
21 should not -- I mean, a 1, I'm sorry. I don't
22 mean 0.1, a 1, right?

1 So, what we understand about
2 readmission is that in fact the patient
3 characteristics don't add a lot to model.
4 Now, the hospital's readmission rate tells you
5 a lot about what's happening to the patients
6 and patient characteristics add a little bit
7 of information there. They do tell you
8 something about --

9 CO-CHAIR TIRSCHWELL: I just want
10 to interrupt for one second. It seems like
11 you're using this low C statistic, a crutch
12 that that implies that it's more the hospital-
13 related factors when in fact I would submit
14 that your information is much more imperfect
15 in predicting this. And it's not just that
16 the hospital factor is a greater effect. So
17 I don't really think you can use that as a
18 crutch for why your C statistic is low.

19 DR. BERNHEIM: So I can say a few
20 more things about that. I mean, a number of
21 models have looked at readmission rates.
22 There was a recent review of them. Nobody

1 finds patient factors are particularly good
2 predictors of readmission. So I mean you may
3 disagree that it's hospital factors, but it
4 does not appear to be patient factors. You
5 can look at it in a lot of different ways, not
6 our models alone although we've now done this
7 a number of times.

8 The other thing is just to
9 separate the signal-noise reliability thing,
10 we look at reliability in a different way and
11 we do find that we evaluate a hospital time
12 and time again similarly, right? So the
13 signal about the hospital is the same time and
14 time again. We take half the patients
15 randomly and we assess the hospital with half
16 the patients and then we assess the hospital
17 with completely different set of patients and
18 find the same information.

19 This is the challenge for people
20 with the readmission measures. I mean, the
21 other thing I will say is so one, we don't
22 expect that patient factors are actually

1 driving readmission rates that much. We think
2 it has much more to do with care, transitions,
3 communication, follow-up and all of those
4 things that we're really trying to spark
5 improvement in.

6 And we are seeing now more and
7 more studies coming out that in fact hospitals
8 make really important patient-centered
9 improvements and readmission rates drop
10 impressively. And I think it doesn't speak to
11 the C statistic but it does speak to the
12 ability of these systems to really improve the
13 patient experience and allow people to stay
14 home.

15 Do you want to add something?

16 DR. DRYE: Yes, I was just going
17 to add talking about it in a slightly bigger
18 picture way. The goal of risk adjustment is
19 really to level the playing field for
20 hospitals, right? Based -- by adjusting for
21 their patient characteristics. And so that's
22 what our model is doing. The C statistic is

1 just a patient-level statistic. It's the
2 patient-level analysis in the model. And so
3 we know whether we use chart data or we use
4 claims data we can level the playing field,
5 that is we can put all the hospitals on a
6 level playing field, but compared to mortality
7 and other clinical outcomes, readmission rate
8 is -- you're never going to get a good C
9 statistic. What you've accomplished is you've
10 made the measure fair for hospitals.

11 MEMBER WADDY: So, going back to
12 the comment before last, it does seem like the
13 -- it does seem like patient statistics or
14 patient characteristics can certainly play a
15 role. Is this me?

16 CO-CHAIR TIRSCHWELL: Could the
17 people on the phone please mute or not step
18 outside of the airplane anymore?

19 (Laughter)

20 MEMBER WADDY: Such things as, you
21 know, if a patient is for some reason non-
22 compliant with their medications and they come

1 back in with pulmonary edema or they decide
2 not to take their antithrombotic then they
3 could come back in with a stroke. And so I
4 mean those things are very complicated and
5 they certainly can also be tied into hospital
6 characteristics as well, but they aren't
7 mutually -- they're neither mutually exclusive
8 nor completely encompassed by evaluating at
9 the facility level.

10 CO-CHAIR TIRSCHWELL: Response
11 from the developers?

12 DR. DRYE: Sure. That's a really
13 good point and I just try to separate a little
14 bit further the goals of risk adjustment which
15 is we're evaluating what we're doing to level
16 the playing field, and other patient
17 characteristics. We're assessing -- for the
18 model, the risk adjustment model we're just
19 looking at patient clinical characteristics
20 and demographic, when they arrive in the
21 hospital. And so we're not addressing patient
22 behaviors.

1 And in the context of readmission
2 measures we're -- there's a lively discussion
3 about patient behaviors and certainly patient
4 behaviors influence risk of -- I don't, you
5 know, I can't give you how much they influence
6 it but I agree with you that they would
7 influence risk of readmission. More compliant
8 patients are less likely to come back.

9 And that's one of the myriad of
10 factors that we understand hospitals can
11 influence. They don't have full control over
12 it but they can influence it by medication
13 reconciliation, clear discharge instructions
14 providing better support post discharge. So
15 it's a factor hospitals can influence that we
16 don't want to -- we wouldn't want to adjust
17 for it anyway. Yet we, you know, agree they
18 don't have full control over it.

19 CO-CHAIR TIRSCHWELL: I guess, you
20 know, some of the arguments you make about the
21 hospital and the patient factors. And I don't
22 know the literature or whether it exists on

1 this. So if you did go ahead and designed a
2 perfect model that included those factors I
3 guess you're suggesting that those C
4 statistics would be vastly higher. Is there
5 any evidence of that?

6 DR. BERNHEIM: You mean if you
7 designed a perfect model that accounted for
8 nursing care, communication, collaboration,
9 appropriate discharge care? I mean, I don't
10 think anybody can design that model.

11 CO-CHAIR TIRSCHWELL: But even
12 partway there?

13 DR. BERNHEIM: I mean, I think if
14 you add complications into the model you would
15 probably learn something but you erase part of
16 the signal. I mean, that we have seen.

17 CO-CHAIR TIRSCHWELL: Done that.

18 DR. BERNHEIM: We haven't done
19 that. That has been done in other settings
20 where the complications of care.

21 But a lot of the things that we
22 believe are really influential are not easy to

1 measure individually which is why in this case
2 an outcomes measure is so important for
3 quality improvement because there aren't, you
4 know, the process measures that have tried to
5 get at this have had a very hard time
6 discriminating against -- between truly good
7 care and not. And so I think that's the gap
8 that this measure helps to fill.

9 CO-CHAIR TIRSCHWELL: But it seems
10 there's an implicit assumption that the
11 hospitals can have a big effect and you're
12 judging the quality of the hospital care on
13 their, you know, that they have the ability to
14 really affect this readmission rate. And I
15 guess I don't know that that's -- I don't know
16 that that's true. That's a bit of a leap of
17 faith. And you know, whether the C statistic
18 is the right way to try to determine that or
19 not I don't know. But I'm just --

20 DR. BERNHEIM: Right, I mean these
21 are -- sorry, go ahead. No, no, it's two
22 different questions I think. But I would re-

1 frame the implicit leap slightly. We do know
2 that hospitals can influence this because we
3 are starting to see evidence. And they, you
4 know, those studies are percolating out in a
5 lot of places. And we do know that hospitals
6 currently have not focused on these key
7 components which lead to increasing the risk
8 of readmission that have to do with patient
9 education and reconciliation and really
10 communication across providers and
11 coordination.

12 CO-CHAIR TIRSCHWELL: Don't say
13 patient education because --

14 DR. BERNHEIM: Oh, sorry.

15 CO-CHAIR TIRSCHWELL: We disavowed
16 that measure yesterday.

17 DR. BERNHEIM: Forget I said that
18 word.

19 CO-CHAIR TIRSCHWELL: All right,
20 let's go to some more comments. Mary?

21 MEMBER VAN DE KAMP: I just had a
22 question. The re-hospitalization rate is an

1 aggregate now for hospitals and yet we're
2 looking at it for diagnosis for stroke. Is
3 the intent then to look at a re-
4 hospitalization rate specific to the kinds of
5 diagnosis or discharge?

6 For instance, you'd have a
7 different re-hospitalization rate for an
8 ischemic stroke than you would have for
9 cardiac? I'm confused maybe in the overall
10 intent long-term. It's specific to diagnosis,
11 is that what you're saying?

12 Looking at it -- like I spent a
13 lot of time in long-term care facilities and
14 looking at re-hospitalization. And I'm
15 looking to see if what the patient is
16 currently -- diagnosis is is impacting a
17 different rate. So you're going to have a
18 higher re-hospitalization rate for a stroke
19 than you would for pneumonia.

20 DR. BERNHEIM: So I want to make
21 sure I understood your question. The measure
22 looks at patients whose initial admission was

1 for an ischemic stroke and evaluates whether
2 they have any unplanned readmissions
3 regardless of the cause. But I'm not sure
4 that I answered your question.

5 MEMBER VAN DE KAMP: So as you
6 take that out to the discharge location and
7 now you have, you know, a skilled nursing
8 arena that has a number of different diagnoses
9 that, you know, hospitals are looking at for
10 re-hospitalization rate. Is the rate
11 benchmark going to be different per diagnosis
12 for that re-hospitalization rate?

13 DR. BERNHEIM: The way that this
14 measure is designed the benchmark will be
15 against other patients who had an ischemic
16 stroke hospitalization.

17 CO-CHAIR TIRSCHWELL: This one is
18 specific to the diagnosis at the time of
19 hospitalization? I think later in the
20 competing discussion there's a more general
21 readmission one. All right, never mind.

22 MEMBER VAN DE KAMP: I think in

1 the environment that we're in right now we
2 hear re-hospitalization rates kind of
3 generically thrown around as what, you know,
4 what's your re-hospitalization rate. And they
5 don't pull it apart per diagnosis.

6 CO-CHAIR TIRSCHWELL: Well, just
7 the measure that's before us is specific to
8 ischemic stroke.

9 MEMBER VAN DE KAMP: Right, so I
10 guess I'm asking -- I guess I'm probably in
11 usability now that I'm talking that way.

12 CO-CHAIR TIRSCHWELL: Okay. Okay,
13 thank you.

14 MEMBER VAN DE KAMP: Sorry.

15 CO-CHAIR TIRSCHWELL: Dan?

16 MEMBER LABOVITZ: We've had some
17 access to some Medicare data at our hospital
18 and what we've found is that readmission very
19 much depends on things that the hospital does
20 have control over, but not in the way you
21 think. If we pick the right subacute
22 rehabilitation facility, the readmission rate

1 is much lower because that rehab facility has
2 a doctor on staff, has a system that works
3 well, and may not be the most expensive one
4 but it's better at taking care of its
5 patients. And if the hospital picks the right
6 place your readmission rate is lower.

7 Hospital has no incentive to pick
8 the right place right now. It has the
9 incentive to pick the place that will take the
10 patient fastest. And I think what we're
11 really talking about here is that stroke is
12 not something that's just an episode of care.
13 It's not the hospital admission. It's a
14 process that unfolds over weeks and months.
15 But probably the place that has the most
16 impact on how that unfolds is the hospital
17 where the patient starts.

18 My hospital gets to pick which
19 rehab facility the patient goes to and I think
20 we're just beginning to look at that. But
21 what we're discovering is yes, our quality is
22 pretty bad there because we're running after

1 a dollar in this direction. We're not
2 motivated to go after it in another direction.

3 I think this is a good start, but
4 I do have some concerns. There are things
5 that --

6 CO-CHAIR TIRSCHWELL: Excuse me,
7 sorry to interrupt. Can the people on the
8 phone just mute their lines, please? Or
9 Operator Amy, can you mute those lines? Thank
10 you. Dan, sorry.

11 MEMBER LABOVITZ: I think there
12 are some things that I maybe haven't studied
13 this enough or didn't spot that I think really
14 do have an impact on risk of readmission that
15 need to be accounted for lest we hurt
16 hospitals that are doing a good job or
17 introduce bias.

18 I think there are community-based
19 factors that influence a patient's risk of
20 readmission. And I'm wondering if that's been
21 looked at, if that's been evaluated here.
22 Even zip code of origin might have an impact,

1 and I think insurance status makes a
2 difference.

3 I know that the patients I
4 discharge home with really abysmal support
5 because they're undocumented and I can't get
6 them a thing. But I can't keep them in the
7 hospital forever because the vice president of
8 finance will call me the next day. Is that
9 accounted for here? And that's not the
10 hospital's fault, but it is the hospital
11 reality.

12 CO-CHAIR TIRSCHWELL: Thank you.
13 Ramon?

14 MEMBER R. BAUTISTA: One thing I
15 like about your measure, it actually has at
16 least a sincere attempt to try to level the
17 playing field across different providers and
18 hospital systems. And being it is admission
19 there's partly a leap of faith maybe here in
20 accepting this measure. And maybe a few years
21 from now we can find out if it really works or
22 not.

1 A relatively minor question
2 though. Because it is Medicare data we're
3 looking at you can actually trace readmissions
4 to another hospital that takes place, right?
5 And ding the first hospital in that regard,
6 right? Okay, thank you.

7 CO-CHAIR TIRSCHWELL: Therese?

8 MEMBER RICHMOND: I was on the
9 work group and I was one of the "insufficient"
10 people. I'm feeling more comfortable with
11 this measure.

12 While I don't think that it is a
13 perfect measure by any stretch of the
14 imagination, I do think that looking at
15 hospital readmissions there's a growing
16 science in models of care that could reduce
17 readmission in patient populations, congestive
18 heart failure, vulnerable older adults, et
19 cetera. So I think from I guess both
20 importance but also a validity perspective
21 this is probably an important measure.

22 CO-CHAIR TIRSCHWELL: Michael?

1 MEMBER KAPLITT: Yes. So you
2 know, to Dan's point I would just like, you
3 know, an answer. It seems to me like your
4 risk adjustment is pretty similar to the last
5 measure except risk adjustment for death is
6 very different than risk adjustment for
7 readmission. Because there seems to be no
8 accounting for the post-discharge risks which
9 there are which is very different than death
10 which, you know, we understand. That's more
11 reflective of your baseline risk. So he
12 mentioned a whole series of them. So, was
13 there a discussion about post-discharge risks?
14 And you know, and if so then why are they not
15 accounted for?

16 DR. BERNHEIM: So I thought Dan
17 had some really good comments that got at the
18 nuance of this issue, right? So on the one
19 hand, you know, it's not our fault, it's the
20 rehabilitation center. On the other hand, we
21 are the ones who are in the position -- "we"
22 being a hospital -- to evaluate the post-

1 discharge setting and make sure that when we
2 have provided excellent care to patients we
3 are not then sending them to a place that is
4 going to unravel that.

5 And so it is not a simple
6 situation and the way the health system is
7 designed right now is very segmented, siloed.
8 And hospitals can't control everything that
9 happens. But if you think about a nidus for
10 this measure and who is in the best position
11 to take accountability I think there will be
12 growing efforts to have community agencies
13 also taking some responsibility. I think you
14 will see that and may already. We feel like
15 the hospital has an enormous ability to affect
16 this and we are seeing that.

17 MEMBER KAPLITT: But with all due
18 respect, I mean I agree with you that, you
19 know, you don't want to oversimplify it but
20 the whole exercise here is somewhat
21 oversimplified, right? Because we're going to
22 give people a single number that says that

1 this hospital may be better at this than this
2 hospital. But then we're saying that, you
3 know, well, you know, we understand that
4 hospitals have issues and they can control
5 some of this.

6 And I think that you're way
7 overstating what the hospital can control
8 because it varies by state. There are state
9 laws that influence things, right? Patients,
10 families have a right to make a choice as to
11 where they want to go even if we disagree with
12 them. You know, there are the realities as he
13 says about different patients having different
14 financial situations that influence their
15 post-discharge care. We can give two patients
16 the exact same level of care and yet what
17 happens to them afterwards really has very
18 little to do and very little control by the
19 hospital.

20 So what we're doing is saying
21 okay, in a world where the hospital is put in
22 a situation where they have limitations on

1 what they can do, we're going to ignore
2 factors that could influence this and make the
3 assumption that the hospital has more control
4 than they may have.

5 And I think that's the concern
6 that's being expressed here. Not that we
7 disagree that this is ultimately not an
8 important measure, we've already voted on
9 that. But the question is how we're taking
10 into account the realities of the world we
11 live in now rather than the way we'd like it
12 to be.

13 DR. BERNHEIM: Right, so I don't
14 mean to oversimplify or be unsympathetic.
15 There is no question that the causal pathway
16 to readmissions is incredibly complex.
17 There's not an easy way to try to tease apart
18 those factors in the post-discharge
19 environment that a hospital can or cannot
20 influence, and it is clear that there are many
21 things that hospitals can do that will reduce
22 risk.

1 And hospitals again are not being
2 expected to go to zero. The question is given
3 the case mix you have how are you doing
4 relative to other hospitals. And I think in
5 that way we're leveling the playing field and
6 doing the best we can in an environment where
7 this is a really important measure.

8 CO-CHAIR TIRSCHWELL: Jack, do you
9 have a comment?

10 MEMBER SCARIANO: In private
11 practice we have what's called -- it's called
12 hospital wars. That if you look in a city you
13 always see billboards up. It says this
14 hospital is actually number one in heart, or
15 this hospital is also number one in heart.
16 And they all use different criteria.

17 Well, I've seen in our city that
18 oftentimes to have an overall better heart
19 rating is that heart problems often get dumped
20 into stroke. If you come in and you have a
21 heart failure you may get confused and
22 oftentimes the cardiologist would say well, it

1 was an actual stroke that actually came in.
2 And as he got bad and as he or CMS came in and
3 actually did an audit and the hospital is now
4 closed because they were doing this.

5 So I think that the overall way
6 you can tease this out is to have like a
7 quality committee in the hospital look at all
8 the readmissions and see, you know, what's the
9 actual cause. You know, is it actually heart
10 failure? Is it actually a kidney failure? Is
11 it dehydration? Because all these things at
12 times are actually being logged in as they're
13 having stroke.

14 CO-CHAIR TIRSCHWELL: Okay,
15 thanks. Helen?

16 DR. BURSTIN: So this is obviously
17 not the first readmission measure NQF has
18 looked at and I suspect it's probably not the
19 last. So I just want to at least give some
20 insights into where this has gone before.

21 So, some of you may know we
22 recently evaluated the all-cause hospital

1 readmission measure and as part of that
2 discussion the board did exactly this
3 discussion. We had this discussion for
4 several hours and ultimately the board put out
5 a guidance statement that I think might be
6 helpful just to put this in context when they
7 ultimately endorsed that measure.

8 And the point was multiple factors
9 affect readmission measures including the
10 complexity of the medical condition and
11 associated therapies, effectiveness of
12 inpatient treatment and care transitions,
13 patient understanding and adherence to
14 treatment plans, patient health literacy and
15 language barriers, and the availability and
16 quality of post-acute and community-based
17 services particularly for patients with low
18 income. Readmission measurements should
19 reinforce national efforts to focus all
20 stakeholders' attention and collaboration on
21 this important issue.

22 So I think there is a recognition

1 readmissions are multifactorial, there are
2 many factors that go into play. And I think
3 the recognition was measuring it at a hospital
4 level will probably enhance more of the
5 community collaboration that I think really
6 you just talked to, Dan, in terms of
7 understanding what are available in terms of
8 community resources and others.

9 So I just wanted to put that on
10 the table. This isn't a new issue but it
11 certainly is something we've spent a lot of
12 time talking about over the last few months.

13 CO-CHAIR TIRSCHWELL: Okay.

14 Risha, final words?

15 MEMBER GIDWANI: Before I begin
16 speaking can I ask that we bring up Table 10
17 on page 36 of the methodology report?

18 So, I share a lot of David's
19 concerns with the poor C statistic and that to
20 me is actually quite concerning. And
21 developers, your response to us is saying that
22 the rationale for the poor discriminative

1 ability is hospital-level characteristics, but
2 I just don't see the data for this. I'm not
3 sure whether this is really a poor C statistic
4 because the model isn't accounting for enough
5 patient-level factors or because it's
6 correctly excluding hospital-level factors.
7 And I'd like to see some evidence in support
8 of your statement that it's because of the
9 lack of hospital-level factors.

10 DR. HERRIN: So first, what are we
11 looking at on the table that concerns you?

12 MEMBER GIDWANI: Well, these are
13 all of the patient-level factors that are in
14 your model and so I want the clinicians in the
15 room to be able to see this. I'm not a
16 clinician but maybe this is -- if this is
17 considered a comprehensive list by our
18 clinicians I'm happy to go with that, but if
19 there are some patient-level factors that are
20 not included here then that would point
21 towards the need to include these in the model
22 rather than state that the poor discriminative

1 ability is completely due to no hospital-level
2 characteristics being included.

3 CO-CHAIR TIRSCHWELL: Along those
4 lines I guess I'd ask has anybody done a
5 similar readmission model where you had, like
6 for the mortality one you said you compared to
7 ones with, you know, stroke severity nicely
8 coded and characterized. And did that lead to
9 a better ability to predict readmission?

10 DR. BERNHEIM: So we did the same
11 chart validation for this measure and the
12 medical record model actually had a slightly
13 worse C statistic. And they were correlated
14 at 0.99.

15 CO-CHAIR TIRSCHWELL: Did the
16 stroke severity -- was that a significant
17 predictor of readmission at all? Because I
18 think that's one of the main things that's
19 missing from administrative data.

20 DR. BERNHEIM: Right, that's the
21 concern that people raise. When you look in
22 the literature which is not yet deep on what

1 predicts readmissions and stroke, it turns out
2 that stroke severity is only variably showing
3 up as an important predictor which is
4 surprising.

5 CO-CHAIR TIRSCHWELL: Risha?

6 MEMBER GIDWANI: I just wanted the
7 developers to respond to the original
8 question.

9 CO-CHAIR TIRSCHWELL: Go ahead.

10 DR. HERRIN: So we're talking
11 about the C statistic. And I understand that
12 the 0.60 looks low but if you think about the
13 fact that we're measuring hospitals and the
14 first thing you might do to measure a hospital
15 is just calculate the raw rate. Take the
16 number of readmissions and divide it by the
17 number of patients, you get a percentage. You
18 can use that as a model also to predict what
19 happens to each patient. And if you do that
20 the C statistic is -- at the patient-level is
21 something like 0.52. I mean it's not much
22 better than chance. I think we'd all agree

1 that at the hospital level you actually have
2 a pretty good first, you know, first order
3 estimate of the what the hospital rate is.

4 All we're doing is taking that
5 rate and adjusting it. It may not look like
6 we have a very good prediction at the patient
7 level but I think that what we end up with a
8 hospital rate is, you know, is an improvement
9 on just the raw rate. That's what you want.

10 And the fact that we reach 0.6,
11 the comparison is not -- we're not trying to
12 again predict what happens to individual
13 patients. We're trying to measure what is
14 happening at the hospital level.

15 CO-CHAIR TIRSCHWELL: Risha?

16 MEMBER GIDWANI: I think my
17 concern stems from the fact that given that
18 this is a poor C statistic, if it is entirely
19 -- the distance between 0.6 and 1.0 is
20 entirely due to hospital-level factors, okay,
21 that would be information for the hospitals if
22 you know, any data were actually being

1 collected and presented to them on this but I
2 think that's a usability issue rather than
3 validity. But it seems to me that you have
4 that opportunity, that if you have the medical
5 record you could actually include the
6 hospital-level factors of the transfer process
7 and some aspect of communication and other
8 variables that you consider to be hospital-
9 level and see whether using your medical
10 record model your C statistic was greatly
11 improved.

12 And if that was the case then all
13 of your other variables, your patient-level
14 variables were the same between your medical
15 record model and your administrative model.
16 And the only difference was the inclusion of
17 hospital-level information in the medical
18 record model. Then I think you could make
19 that conclusion, that the poor C statistic is
20 due to the lack of hospital-level information.

21 But given that the opportunity
22 existed to do that we don't see any data here.

1 I'm just concerned. I think that that
2 statement that's being made, maybe it's true
3 but the evidence isn't there to back it up.

4 CO-CHAIR TIRSCHWELL: Response?

5 DR. BERNHEIM: I'll just point
6 again to the fact that there's been a number
7 of models, not by our group but by other
8 groups looking at this and consistently this
9 is the finding when you try to look at the
10 hospital-level readmission patient factors
11 adjust. Patient factors that you would want
12 to adjust for, patient factors that are
13 present on admission do not seem to be
14 particularly important in evaluating. So I
15 mean I just, I know that makes the committee
16 uncomfortable but it seems to be true across
17 the board.

18 I think what you're proposing we
19 could try to look at is to assess what
20 variables at the hospital level we could
21 collect that we think might be important. You
22 could also look at things outside of the

1 hospital potentially. It's a challenging
2 project. I mean again, I think we all believe
3 that what is predicting readmissions is really
4 a complex web of missed opportunities to
5 coordinate care.

6 And so to adequately try to put
7 all of those into the model is not a simple
8 job and I think it's why people haven't done
9 it. But we can go back to our group and think
10 a little bit about whether there's ways that
11 we can sort of prove that hospital factors
12 being added would increase the C statistic if
13 that would be useful.

14 CO-CHAIR TIRSCHWELL: Yes, and you
15 know my --

16 DR. DRYE: I just want to clarify
17 then the goal there is not to change the
18 measure because as we talked about we --
19 patient factors do matter. We don't, like
20 Jeph was pointing out, the C statistic is not
21 0.5, it's 0.6. It's important to adjust for
22 patient factors on admission the way we do.

1 We would not be fair to hospitals if we didn't
2 do that. So, all our models, our chart-based
3 model, our claims models, other people's
4 readmission models, this is as good as they
5 get with the C statistic.

6 So to clarify what -- for
7 readmission. So what you're asking is, you
8 know, can we do an investigation that gives
9 you more confidence that hospital factors that
10 we can get our hands on influence the outcome
11 of readmission. And it's kind of an ancillary
12 study saying is readmission really --

13 MEMBER GIDWANI: I'm sorry, I
14 don't think it is ancillary because the
15 response to our concern over the low C
16 statistic was that it's because hospital-level
17 factors are appropriately not included. And
18 so I think that's an important thing to test
19 before stating that that's the reason.

20 CO-CHAIR TIRSCHWELL: It's sort of
21 the foundation that the potential improvement
22 is -- I mean, the idea is that you're going to

1 improve care here by affecting the hospital-
2 level factors which are the explanation. And
3 I guess, you know, we've held other measures
4 up to show the evidence that what we're trying
5 to influence here, hospital-level care, is
6 clearly shown to affect the outcome of
7 interest.

8 DR. DRYE: I want to -- I think my
9 colleague Harlan Krumholz is on the phone and
10 wants to say something. But by "ancillary" I
11 don't mean that it's irrelevant, I just mean
12 it's not about changing the measure, it's
13 about thinking about readmission as a measure
14 concept. And I think the kinds of things you
15 would want to get at, we've been talking
16 about, like medication reconciliation,
17 coordination, rapid response, complications in
18 the hospital because those affect readmission,
19 you know, safety, and then all the
20 transitional and post-acute care. They're not
21 sort of easy, quick things we could grab for
22 hospitals and throw into the model to look at

1 that, but I want to -- let me let Harlan
2 follow on.

3 DR. KRUMHOLZ: Thanks, Elizabeth.
4 And I appreciate -- I'm sorry.

5 CO-CHAIR TIRSCHWELL: Go ahead.

6 DR. KRUMHOLZ: Okay, thanks. This
7 is Harlan Krumholz and I'm a member of the
8 Yale team. And I appreciate the opportunity
9 to speak to the group. Can you hear me
10 clearly?

11 CO-CHAIR TIRSCHWELL: Yes.

12 DR. KRUMHOLZ: Great. This issue
13 of course as Helen has said has come up
14 repetitively about the C statistic and it's
15 one that we have thought deeply about. It
16 defies easy empirical analysis by putting in
17 hospital interventions because of the
18 heterogeneity of the way in which these
19 interventions are applied.

20 See how teaching, for example,
21 discharge instructions doesn't turn out to be
22 a very good measure and doesn't turn out to

1 indicate at all any better outcomes. Yet all
2 of us believe that really good teaching likely
3 has a role to play in helping improve patient
4 outcomes and that's because when you study
5 care you see immense variability in the way in
6 which that process is applied. So it becomes
7 very difficult to take hospital
8 characteristics and -- them at covariates in
9 this model and try to explain some of the
10 variation because they're all complex.

11 Now with regard to this issue of
12 the low C statistic, there -- I think -- I
13 just want to review what are some of the major
14 points here. One is that remember we are
15 purposely tying the risk adjustment to
16 admission because things that happen in the
17 hospital, adverse events that happen in the
18 hospital we would not want to adjust for and
19 give a hospital credit for a sicker group of
20 patients because of -- complications that may
21 occur in the hospital many of which may be
22 preventable in a lower risk environment. So,

1 it is one of the things that makes it almost
2 by nature going to be able to predict
3 readmission is the distance in time from the
4 time zero with this discharge. So that's one
5 thing.

6 The second thing is that no matter
7 what data source we have used around
8 readmission we continually find that patient
9 characteristics are far from the dominant
10 influence on who gets readmitted. It has led
11 to this appreciation of thinking about people
12 leave at a certain risk strata. Each
13 environment is associated with risk.

14 And when we look deeply at our own
15 institution we find an embarrassingly high
16 number of opportunities here to improve. That
17 is, we find that we are often sending people
18 home -- I won't say often, but we found we
19 were sending people home with two beta
20 blockers. We had forgotten to give the
21 antibiotic for the patient who was admitted
22 with pneumonia. We have given people a liter

1 of fluid the day before they go home after
2 heart failure. We have failed to give them a
3 path towards appointments after they leave.
4 We've done a lot of things that actually we
5 think increase their risk of readmission and
6 in fact for the three publicly reported
7 measures we've historically been higher than
8 expected. And we have instituted a lot of new
9 approaches and our readmission rate is
10 dropping.

11 I spoke to 600 Premier hospitals
12 just 2 weeks ago in Nashville. And as I made
13 my way around the room I'm hearing about
14 people recognizing that they've got these same
15 deficiencies. And they know they don't own
16 the entire 30 days, and they know that there
17 are many things that are beyond their control.
18 But they're also seizing the things that are
19 within their control and they're recognizing
20 not that they can eliminate readmissions, but
21 they can lower the risk of patients, make it
22 safer for them to go home, be more secure in

1 that the systems that are being implemented
2 are going to smooth that path for those
3 patients. And that's what makes us feel
4 confident about these measures.

5 It's true that it's difficult to
6 predict. It's true that there are many things
7 that are beyond a hospital's control. But
8 when you look deeply at the hospitals we do
9 not do well at this. And this is now shining
10 the light on it and hospitals that are higher
11 than expected commonly have more problems.
12 And we're seeing people being able to make
13 movement by focusing on that. And that's why
14 we remain strong in our belief that this is an
15 important measure.

16 CO-CHAIR TIRSCHWELL: Thank you
17 very much. Salina?

18 MEMBER WADDY: So, the first
19 question I'd like to ask is in response to
20 David's question a few minutes ago regarding
21 severity. Since this is really, as the caller
22 mentioned, the time zero is date of discharge

1 is the severity the --

2 CO-CHAIR TIRSCHWELL: Day of
3 admission I think.

4 MEMBER WADDY: No, no, according
5 to this it says date of discharge.

6 DR. BERNHEIM: We only assess
7 patient factors up till the time of admission
8 but the 30-day time window starts at
9 discharge.

10 CO-CHAIR TIRSCHWELL: Oh okay,
11 sorry.

12 MEMBER WADDY: Right, that's why I
13 was wondering if the severity that you're --
14 that you've looked at, is that severity at
15 admission which it sounds like. It seems like
16 it would be more appropriate to have severity
17 at time of discharge.

18 CO-CHAIR TIRSCHWELL: Well, they
19 don't really have severity at either time.

20 DR. BERNHEIM: But the concept
21 that you're trying to get at, again, we are
22 trying to understand a multitude of factors

1 that are going to affect the likelihood that
2 a patient's going to get readmitted. Some of
3 those happen during the hospitalization and
4 those are the ones that are more under a
5 hospital's control.

6 So if a patient is more severely
7 ill at their time of discharge, let's say we
8 failed to do aspiration precautions and
9 they've ended up sicker we would not want to
10 risk-adjust that away. So the risk
11 adjustment's time, if you will the risk
12 adjustment time zero starts at admission but
13 we want to assess a standard period for
14 readmission so that needs to start at
15 discharge so that we don't have variable
16 length of potential readmissions.

17 CO-CHAIR TIRSCHWELL: Dan?

18 MEMBER LABOVITZ: I'm just
19 offering up some thoughts in response to
20 Risha's points which are I think is we're
21 getting back to the C statistic of a lousy
22 0.6. And I think the developers are

1 rightfully admonished for suggesting that the
2 remaining distance to 1.0 is just hospital-
3 based factors. I think we just don't know.

4 But I also would suggest that our
5 capacity to capture these things in models as
6 the -- I don't remember his name, but the
7 developer who just spoke fairly eloquently
8 said you can capture -- you can record all
9 kinds of data but it doesn't necessarily have
10 meaning, and it doesn't necessarily have
11 anything to do with quality or what you're
12 really delivering.

13 And I think one of the advantages
14 of this look is it's two hard points. You've
15 got a hospital and you've got a real rubber-
16 meets-the-road readmission rate. And I think
17 that there are very, very significant --
18 there's a real capacity for the hospital to
19 influence that rate, not totally, not even
20 close to totally. The patient will get hit by
21 a bus, bound to happen, and there are going to
22 be other factors in the community that

1 influence it. But this is an area where
2 there is tremendous opportunity to improve and
3 I don't really care how you do it. Maybe it's
4 throwing an education pack at the patient,
5 maybe it's writing "You shouldn't smoke" on
6 every discharge summary, or maybe it's
7 establishing better connection between the
8 nursing home and the physician who discharged
9 the patient and making sure that happens. And
10 yes, you get an administrator who can answer
11 the phone and get you to the right doctor,
12 this sort of thing. Hospitals will find a way
13 to do it if we shine a light on it.

14 CO-CHAIR TIRSCHWELL: Yes, so Dan,
15 if I can just reiterate that maybe it's not
16 the particulars of the model that are the key
17 thing here, it's that we're talking about it
18 at all and that that's leading engagement in
19 hospitals and maybe even beyond their borders
20 to try to reduce these rates. Jolynn?

21 MEMBER SUKO: Well, a very similar
22 point. But as you think about conceptually an

1 outcome measure it's to drive the discovery of
2 the interventions that may influence it. And
3 so when you look at this, this is driving
4 discovery even more so than mortality of
5 interventions that we believe will influence
6 it. And so even though the C statistic isn't
7 perfect like no model is, when you look at
8 2b.5 Meaningful Differences I think we're
9 finding that with this measure.

10 CO-CHAIR TIRSCHWELL: Salina?

11 MEMBER WADDY: So just a follow-up
12 on Dan's statements. Certainly there are
13 things that the hospitals can do, some things
14 that are out of their control but there are
15 things that they can do better. Unfortunately
16 there's a paucity of tools that we actually
17 know that work.

18 And so one thing that's currently
19 going on within NIH is to better develop tools
20 that kind of bridge the gap from the time a
21 patient is in the hospital, the use of
22 behavior change interventions that are not

1 only behavior change for the patient but also
2 behavior changes for the hospital as well as
3 the primary care provider and the utilization
4 of things such as community health workers to
5 try to solidify the lessons that were supposed
6 to be learned in the hospital.

7 And so eventually you'll be able
8 to -- people will be able to use these tools
9 and whether or not a hospital system actually
10 adopts one tool or the use of no tools is
11 going to separate out the quality of care
12 between those types of systems hopefully.

13 CO-CHAIR TIRSCHWELL: Okay, Bill
14 and then maybe last words.

15 MEMBER BARSAN: Just one quick
16 question about the variables. Did you all
17 look at any other mental health variables
18 besides dementia?

19 CO-CHAIR TIRSCHWELL: They're
20 probably bundled into those giant bundles I'm
21 guessing.

22 DR. BERNHEIM: Yes, I'm trying to

1 remember which ones came into this model.
2 Yes, so again, the mental health variables are
3 bundled into a couple of different grouped
4 ICD-9 codes. And in this case what you see up
5 there is what was found to be consistently
6 statistically significant for the model.

7 CO-CHAIR TIRSCHWELL: Risha?

8 MEMBER GIDWANI: I just want to
9 clarify my concern here is not only with the
10 C statistic. I think the developers'
11 explanation of why a C statistic can be low
12 would be valid if they provided evidence to
13 suggest that the entirety of the difference or
14 the majority of the difference between 0.6 and
15 1.0 is due to hospital-level factors.

16 And given the fact that they did
17 have an opportunity to study this difficult
18 though it might be, and I acknowledge that it
19 is, but also the repercussions of these
20 measures are quite large and I think that
21 warrants a very thoughtful and careful look.
22 And given the fact that they did have medical

1 record data and somewhat, well, really
2 inability to actually study this and
3 operationalize this with good resources, but
4 the data weren't presented. I don't think the
5 anecdotal evidence that were presented by the
6 gentlemen on the phone are sufficient for what
7 a National Quality Forum endorsement would
8 require.

9 DR. BERNHEIM: Can I just respond
10 briefly to what's available in the medical
11 records? Which again, as we're talking about
12 we don't think that the factors are things
13 like is this a teaching hospital or not,
14 right? I mean again, this discussion has been
15 I think a very thoughtful one about the
16 complex web of things that are probably
17 contributing.

18 And so in order to examine this we
19 would need -- when we have chart data what we
20 have is data that's been abstracted from
21 charts that looks at patient factors. We
22 don't have data that was abstracted that looks

1 at the quality of the discharge instructions
2 or many of the things that people have been
3 referring to here that might be important.

4 And again, we can, you know, we
5 can think with you about whether there really
6 are variables that would help to answer this
7 question, but it has not been taken lightly.
8 It's just a pretty tough task.

9 CO-CHAIR TIRSCHWELL: Any final
10 comments before we move to vote, Risha? Last
11 comment?

12 MEMBER GIDWANI: I would just say
13 then that points to insufficient evidence as
14 to the difference between a value of 0.6 and
15 1.0 as opposed to us just concluding that it
16 should be due to hospital-level factors. I
17 don't think there's the data then.

18 CO-CHAIR TIRSCHWELL: Okay.

19 DR. DRYE: Can I just add one --
20 just one? I think it's relevant to this issue
21 of whether there are hospital-level factors
22 that affect the outcome is that there is a

1 published peer-reviewed literature showing
2 effective interventions by hospitals in
3 lowering readmissions. So we know hospitals
4 can affect the outcome of readmission.

5 CO-CHAIR TIRSCHWELL: Okay. And
6 final comment from Karen?

7 DR. PACE: Right. I just want to
8 make a few points about our criteria and some
9 of the points that have been brought up.

10 One, first of all about our
11 preference for outcome measures and the
12 acknowledgment that the reason we don't ask
13 for the developers to provide all of the
14 detail of the body of evidence like we do for
15 process measures is because there are multiple
16 processes and care interventions that affect
17 outcomes.

18 And so just as was already
19 mentioned that an outcome measure is never
20 going to tell you exactly what to do. It is
21 something that tells you that you need to dig
22 into your data and see for your particular

1 setting and patients what are those
2 interventions. And it is through measuring
3 outcomes that we actually push the envelope to
4 try to find those things. So, that is kind of
5 the essence of our board's direction of trying
6 to get at outcome measures.

7 The other thing as was already
8 mentioned is that there is a growing body of
9 evidence that does exist showing the impact of
10 interventions on readmission rates.

11 And thirdly is that even though
12 the, you know, the C statistic, you can't say
13 that it's all going to be hospital factors,
14 that certainly is part of the explanation.
15 But one of the things to look at in any of
16 these statistics because again our criteria
17 have not set kind of a hard threshold that a
18 C statistic has to be a particular number or
19 a reliability statistic has to be a particular
20 number, but what is it in relationship to
21 norms for that particular outcome or that
22 particular measure or that particular

1 reliability statistic.

2 So I just wanted to kind of bring
3 you back to some of the criteria and the
4 discussions and reasons for the approach that
5 NQF has in their criteria.

6 CO-CHAIR TIRSCHWELL: Okay.
7 Unless there are other burning questions I'd
8 suggest we move to activate the voting for
9 validity.

10 MS. THEBERGE: Twelve moderate,
11 four low, six insufficient.

12 CO-CHAIR TIRSCHWELL: Okay. So
13 then next is usability.

14 MEMBER GIDWANI: With respect to
15 usability the work group had a value of one
16 high, one medium, one insufficient. The
17 rationale for the insufficient was more
18 discussion of how to interpret a predicted to
19 expected value is needed. The developers did
20 provide feedback on this. And I was the
21 person that noted that so I would change my
22 vote.

1 One question I do have though is
2 that if these are hospital-level factors that
3 would need to be intervened upon in order to
4 reduce the readmission rate I don't believe
5 these are actually being captured. So I
6 suppose, is it then correct that if a hospital
7 had a poor -- higher than expected readmission
8 rate they would need to delve into their own
9 records and do their own analyses to decide
10 how to improve that?

11 DR. BERNHEIM: Yes, I think there
12 are some -- again, there are increasing
13 evidence about interventions that are useful.
14 But there is an expectation that the outcomes
15 measures really spark a fair amount of work
16 for the hospitals to understand where they can
17 intervene. And again, probably not just
18 within their own walls.

19 CO-CHAIR TIRSCHWELL: And I guess
20 I would only comment that I remain concerned
21 about the interpretability of a ranking based
22 on something that's not very predictive of the

1 outcome.

2 DR. BERNHEIM: Can I say one
3 quick?

4 CO-CHAIR TIRSCHWELL: Please.

5 DR. BERNHEIM: It's -- Elizabeth
6 was going to go back to the -- again, we're
7 not trying to predict patient-level. But also
8 I would comment that the way these measures
9 have traditionally been used really is not as
10 a ranking, right? I think it's important to
11 know that the way that they have tended to be
12 used in public reporting is simply to identify
13 outliers. So, to identify the hospitals that
14 are doing significantly worse than would be
15 expected given their case mix, but not to sort
16 of say hospital A is one point better than
17 hospital B is one point better than hospital
18 C. That's not the way they've traditionally
19 been used.

20 CO-CHAIR TIRSCHWELL: So you're
21 just ranking the worst ones as worst.

22 (Laughter)

1 DR. BERNHEIM: Sorry, just
2 identifying outliers. Just an identification
3 of outliers.

4 CO-CHAIR TIRSCHWELL: Seems like a
5 ranking. But anyway, that's fine. Risha?

6 MEMBER GIDWANI: I should have
7 asked this question earlier but if a hospital
8 has a value of let's say 1.2 but their
9 confidence interval goes from -- includes 1.0
10 then would they be considered average?

11 DR. BERNHEIM: Yes.

12 MEMBER GIDWANI: Thank you.

13 CO-CHAIR TIRSCHWELL: Any other
14 comments or questions? Mary.

15 MEMBER VAN DE KAMP: I'm going to
16 try my question again then. And maybe I think
17 you helped, Gail. The all-cause re-
18 hospitalization metric that was used, how does
19 this differ from that? Are you looking to
20 then say that re-hospitalization rates may be
21 different as you look at different diagnoses?
22 So if I'm taking a lot of stroke patients I

1 need to be better at that and that would show
2 rather than lumping it into an all-cause
3 bucket that may not really differentiate
4 specialty?

5 DR. BERNHEIM: Right, exactly. I
6 think -- I didn't realize earlier that you
7 were referring to the hospital-wide measure.

8 So, we think that they both have a
9 purpose, that the hospital-wide measure may be
10 an important way of looking at a hospital as
11 a whole and that it is likely that there are
12 going to be a number of things that cross
13 specialties that are important and that have
14 a quality signal at the hospital as a whole.
15 But your neurologist group is going to
16 struggle to use that measure to improve care
17 for their patients. And so there's a real
18 need for quality improvement to be able to
19 look at these things at a condition-specific
20 level. So that would be the use of this
21 measure.

22 CO-CHAIR TIRSCHWELL: Okay.

1 Risha, your thing is still up there. Do you
2 have anymore comments? Okay. Jocelyn?

3 MEMBER J. BAUTISTA: One quick
4 question. Can you clarify, would patients
5 admitted under observation status, would they
6 be excluded?

7 DR. BERNHEIM: Right, the measure
8 is designed to capture patients who are
9 admitted for the index stay as well as for the
10 readmission.

11 CO-CHAIR TIRSCHWELL: So sounds
12 like they would be excluded.

13 DR. BERNHEIM: Right, but maybe
14 that got lost. Yes, you are correct, they
15 would be excluded.

16 CO-CHAIR TIRSCHWELL: Okay. I say
17 we open the voting for usability.

18 MS. THEBERGE: Seven high, eleven
19 moderate, four low.

20 CO-CHAIR TIRSCHWELL: And then
21 feasibility. Any comments? Risha, do you
22 want to say anything?

1 MEMBER GIDWANI: I'll just
2 summarize the scores which were two high, one
3 medium. And I'll remind everyone these are
4 administrative data.

5 CO-CHAIR TIRSCHWELL: Any
6 comments? Let's open the voting, feasibility.

7 MS. THEBERGE: Eleven high, ten
8 moderate, one low.

9 CO-CHAIR TIRSCHWELL: And then
10 overall suitability for endorsement.

11 MEMBER GIDWANI: For overall
12 suitability the work group voted one yes, two
13 no. One work group member noted a preliminary
14 conclusion that this was preliminary based on
15 more details on the modeling process and
16 rationale. Another work group member wanted
17 further discussion on the inclusion or absence
18 of stroke severity in the risk adjustment and
19 the implications of this.

20 CO-CHAIR TIRSCHWELL: Any other
21 comments or questions? Let's go ahead and
22 open the voting up.

1 MS. THEBERGE: Thirteen yes, nine
2 no.

3 CO-CHAIR TIRSCHWELL: Okay, I
4 think we're going to take a 10-minute break.
5 Let's try to be back by 11:20, we'll get
6 started.

7 (Whereupon, the foregoing matter
8 went off the record at 11:08 a.m. and resumed
9 at 11:21 a.m.)

10 CO-CHAIR KNOWLTON: We are moving
11 onto the speech and language measures. And
12 we're going to ask for the developer to make
13 a comment first and then Karen has a comment
14 from NQF. And then we're going to move out of
15 order because Dr. Sheth has a flight he has to
16 catch so we'll be moving 0446 up to the first
17 one. So you can adjust your SharePoints, your
18 documents if you want to. So let's go to the
19 developer first.

20 DR. MULLEN: Good morning,
21 everyone. My name is Rob Mullen and I'm
22 joined by my colleague Dr. Frymark. We are

1 with the American Speech-Language-Hearing
2 Association or ASLHA representing the measure
3 development team.

4 These measures were developed by a
5 team of clinicians and researchers at ASLHA 15
6 or 16 years ago and have been in use for the
7 past 14 years primarily through an ASLHA-
8 sponsored nationwide data clinician system
9 called the National Outcomes Measurement
10 System. So we have been collecting data using
11 these measures for the past 14 years.

12 We currently have about 300,000
13 episodes of speech-language pathology
14 treatment in our data set based on these
15 measures. They are currently used within the
16 context of a National Outcomes Measurement
17 System by approximately 3,000 clinicians and
18 approximately 500 facilities across the United
19 States as well as a smattering of other
20 countries.

21 With NQF endorsement of these
22 measures I believe it was 4 years ago the

1 measures that went into the public domain saw
2 certainly additional use beyond the previously
3 restricted use for the National Outcomes
4 Measurement System. So for the past 4 or so
5 years there has been additional use by other
6 people for other purposes.

7 I think a couple of important
8 things to note is that these measures were
9 developed 15 or 16 years ago not with public
10 reporting in mind. Obviously they've been
11 submitted to NQF for endorsement because we do
12 think they have the potential to be used in
13 public reporting but the initial impetus for
14 developing these measures was to have locally
15 available data for clinicians and
16 administrators to be able to assess and
17 document the functional gains made or not made
18 by patients at the local level to stimulate
19 thinking about quality improvement. And
20 that's primarily how they've been used.

21 The eight measures here represent
22 the eight areas of speech-language pathology

1 treatment most commonly used with stroke
2 patients. In practice the eight measures are
3 not used together and we certainly have never
4 seen a patient for whom all eight of these
5 measures were scored. Typically what we see
6 is that the patient will use -- a clinician
7 will use one to maybe two or three or even
8 four of these measures on a single patient,
9 but they are meant to be separate depending on
10 which of these areas of speech-language
11 pathology relate to that patient's treatment
12 plan.

13 So these measures consist of
14 basically a pre-score and a post-score. At
15 the beginning and at the end of the speech-
16 language pathology treatment episode the
17 patients are scored on these disorder-specific
18 seven-point ordinal scale. So it's important
19 to note that these are ordinal rather than
20 interval scales. And the primary measure of
21 progress we use is the extent to which
22 patients made or failed to make any measurable

1 progress on these scales from admission to
2 discharge from SLP treatments.

3 MS. JOHNSON: Thank you. Just to
4 give you a little bit more background -- thank
5 you, Rob, for that intro to your measures. We
6 wanted to give you from the NQF perspective
7 just a little bit more background on the work
8 that we've done between these developers and
9 us to try to get these ready for you guys to
10 look at. So, if you'll bear with me I'm going
11 to just give you that background now.

12 First of all, the first time
13 around when they submitted their measures we
14 had a lot of questions just like with some of
15 the other developers. And these developers
16 were great in really responding to our
17 questions. So some of our questions included
18 questions about the impact of the measures and
19 also a lot of very detailed questions about
20 their specs. We weren't quite clear about
21 their definition of progress, their time
22 measurement, their exclusions and their risk

1 adjustment methodology. So we did ask them to
2 provide that and for the most part they were
3 able to do that.

4 We also asked for additional
5 detail about reliability and validity testing
6 methods and results. So both of those things.

7 And again, they did respond at
8 length with a lot of things. They told us
9 about impact and they really brought in
10 information from the literature for that. In
11 terms of evidence they, as you know now, these
12 are outcome measures so they were not required
13 to give evidence in terms of quantity, quality
14 and consistency, but they did I think show
15 some rationale supporting their treatment
16 hours I think is how they did it, treatment
17 hours to outcome.

18 They really precisely specified
19 their measures and in terms of data element
20 reliability that's not something that they had
21 to do because they did show data element and
22 validity. So again, that's an NQF guidance

1 there that if you show data element validity
2 we don't require data element reliability.

3 And then finally with their
4 validity testing they have done validity
5 testing at the patient level for the scale
6 that they use, the seven-level scales, and
7 they've also provided some measure score
8 testing, some results from that.

9 All of that said we still have a
10 few unresolved questions and we just wanted to
11 put these out for you guys to be thinking
12 about as you do the discussion. And I think
13 you probably would have even without this
14 slide, but opportunity for improvement. What
15 is the distribution of the performance scores
16 for the measures as specified? And they
17 specified these measures for both clinicians
18 and facilities.

19 And what they gave they did --
20 depending on the measure they maybe have as
21 many -- as few a six or even as many as 24
22 strata. So they did give you differences in

1 patient-level scores for those strata as
2 appropriate, but we also would like to see
3 those for clinicians and facilities because
4 that's how they're specifying that they would
5 use these measures.

6 For reliability if you have as
7 many as 24 risk categories the question there
8 is do you have enough numbers to have, you
9 know, good comparisons.

10 The risk adjustment strategy, the
11 questions that maybe are still there are the
12 analysis that support the risk categories that
13 they have specified as well as a demonstration
14 that the risk adjustment is adequate.

15 And then finally probably the
16 least important question but also an
17 interesting one is how these measures as
18 specified compare to what is currently being
19 reported in PQRS. So with that I'm going to
20 stop and hand it back over to our chairs.

21 CO-CHAIR KNOWLTON: Reminder --
22 Jane, do you have a comment?

1 MEMBER SULLIVAN: Just a point of
2 clarification. Karen, were the questions that
3 were asked prior to or after the work group
4 call?

5 MS. JOHNSON: Some of the
6 questions we asked right before the work group
7 call and Rob and Toby had those answers for us
8 by the work group call and we -- I believe we
9 sent those out to the full committee. And
10 then other ones came after the call.

11 CO-CHAIR KNOWLTON: Okay. A
12 reminder that we are now considering 0446,
13 Functional Communication Measure: Reading.
14 And Raj is going to present for the work
15 group.

16 MEMBER SHETH: Thank you. I think
17 the -- looking at the numbers from the impact
18 the group felt that the data that had been
19 provided, the rationale that about 16.5
20 percent with stroke actually have speech and
21 language services and 25, a quarter of that
22 group failed to make any improvement in

1 progress. And they also, the other rationale
2 for this is that there's disparities between
3 race and gender as an issue to be dealt with.

4 The way in which the numerator was
5 scored was really an increase of one or more
6 levels in the reading score. The denominator
7 had exclusions if there was only one visit.
8 And obviously there was no way to measure
9 whether the score went up or down, stayed the
10 same. So the group as a whole felt on the
11 impact factor that this had a high impact and
12 one felt that this was a low impact.

13 CO-CHAIR KNOWLTON: Questions or
14 comments? David? I thought you were raising
15 your hand.

16 MEMBER SULLIVAN: I have a point
17 of clarification on the denominator exclusion
18 and I noticed this actually last night. For
19 each of these measures the exclusion says
20 "Patients who are not candidates for memory
21 treatment." And I believe that's inaccurate.
22 I believe that it should be for each of the

1 areas of care. So this one should be not
2 eligible for reading treatment, is that
3 correct?

4 DR. MULLEN: That is correct.

5 MEMBER SULLIVAN: Okay.

6 DR. MULLEN: I apologize.

7 CO-CHAIR KNOWLTON: Other
8 questions? Jocelyn?

9 MEMBER J. BAUTISTA: So, the
10 evidence of high impact is basically that
11 there are 15,000 patients who receive these
12 services, is that right? Is there additional
13 information?

14 MS. JOHNSON: This is Karen. That
15 is one of the things that they did add to
16 their submission. So if you were looking at
17 the old submission you wouldn't see the stuff
18 from the literature. It should be in there.
19 No? Okay.

20 CO-CHAIR KNOWLTON: Do we have an
21 open question on that or is it resolved? It's
22 not there?

1 MS. JOHNSON: Let me pull up that
2 one and check and make sure we've given you
3 the right one.

4 CO-CHAIR KNOWLTON: While we're
5 doing that, Michael?

6 MEMBER KAPLITT: Well, I mean mine
7 is basically the same and it's an overarching
8 question that I think is going to be the same
9 thing with each of these because it looks to
10 me from just the few that I've skimmed through
11 that the impact section is pretty much the
12 same from one measure to the next showing the
13 same 15,000 patients about what a big problem
14 it is and then isolating what percent have
15 this particular thing but no real statement of
16 impact as to how each of these specific
17 measures are supposed to impact care. Maybe
18 that data is not in what we're looking at
19 right now.

20 CO-CHAIR KNOWLTON: A.M.?

21 MEMBER BARRETT: So I'll comment
22 and perhaps the NQF staff can add. Since this

1 an outcome measure although we would -- the
2 work group noted that we were concerned about
3 the fact that not many patients have been
4 included in the database that was assessed,
5 that this may be because of the opportunity to
6 further expand the measure rather than because
7 of a limited impact.

8 CO-CHAIR KNOWLTON: Karen?

9 DR. PACE: Yes. So, I know that
10 this kind of maybe in some respects looks like
11 splitting hairs, but in terms of impact
12 opportunity for improvement and evidence, what
13 we're kind of looking -- and these are outcome
14 measures. But what are the numbers of -- I
15 mean, first of all you could look at the
16 numbers of people with stroke who have this
17 particular deficit. And so I guess your
18 question is are they giving specific
19 information for the deficit. It doesn't
20 necessarily have to be in their database.
21 This information could come from national
22 studies or -- and you all would be more aware

1 of the numbers that exist in terms of patients
2 with stroke who have this particular deficit,
3 whether -- go ahead.

4 MEMBER KAPLITT: So what I'm
5 getting at, for example, is a simple thing.
6 So it says that the numerator I think is an
7 improvement of one point or something on this
8 scale, is that right? So where's the evidence
9 that one point is meaningful and will make an
10 impact and matters? And is that one point
11 equal -- is the scale perfectly linear? You
12 know, I mean that's what I mean by impact.

13 DR. PACE: Right. So I think
14 we'll get into that in the specifics of the
15 measure. That's about the validity of the
16 measure as being an indicator of quality. So
17 your question is is a one step up, is that
18 really going to be appropriate --

19 MEMBER KAPLITT: Yes, and maybe
20 it's just a difference of opinion. Like when
21 you say -- to me impact is I want to know what
22 they're defining as being, you know, a change

1 is going to impact.

2 DR. PACE: Right. And I'm just
3 telling you in terms of NQF criteria what
4 we're getting at is impact is the potential
5 numbers of people who could be influenced by
6 this particular measure. So we look at impact
7 and then opportunity for improvement. So even
8 though there would be a lot of people
9 affected, you know, if performance is already
10 extremely high then again there's not going to
11 be much improvement. So you're right, you
12 know, with the --

13 MEMBER KAPLITT: Is there data on
14 that point here?

15 DR. PACE: I think you're --

16 MEMBER KAPLITT: I mean there's
17 2,494 patients, right? How do we --

18 CO-CHAIR TIRSCHWELL: They say in
19 the updated thing, they say there's a million
20 aphasic individuals in the United States and
21 that that's mostly due to stroke, and 30
22 percent of stroke has aphasia. Those are the

1 high-impact numbers I think.

2 CO-CHAIR KNOWLTON: Dan?

3 MEMBER LABOVITZ: I guess the
4 problem I have in terms of assessing impact is
5 that I don't see any evidence that relates to
6 impact here. I see that we've got a problem,
7 we have a lot of aphasic patients. I see that
8 25 percent of aphasic patients don't make an
9 improvement and 75 percent do.

10 But where's the impact? What are
11 we influencing? What are we changing here?
12 What is -- speech-language pathologists are
13 some of my best friends. I love them.

14 (Laughter)

15 MEMBER LABOVITZ: I ask for their
16 help all the time. But I want to see the
17 impact. What are we achieving?

18 CO-CHAIR KNOWLTON: Let's not
19 crosstalk. Let's do this in an orderly way.
20 Mary?

21 MEMBER VAN DE KAMP: Dan, I'm your
22 best friend and as a speech and language

1 pathologist I think what this gets at is
2 beginning to measure the effectiveness of the
3 kinds of treatment procedures we provide to
4 patients. So, until you know that there's
5 improvement made or not improvement made in a
6 certain disability or area of focus you can't
7 look back to say what treatment was provided
8 that caused that patient to do better or what
9 comorbidities caused that patient.

10 So, until you can start to measure
11 what we would all agree upon would be certain
12 levels of performance you can't go back to
13 look to see what actual procedures were done
14 that got a better outcome than another. So
15 two speech pathologists doing whatever we
16 think is right, we can't really judge or look
17 back to say what was actually the best
18 practice in that treatment. So that's -- the
19 impact is the quality of the speech and
20 language services that are provided. And then
21 as an industry or a company you can start to
22 measure.

1 It's just like, you know, you look
2 at the care tool that CMS is looking at. It's
3 looking at a tool to measure outcomes. And
4 right now we don't have a standardized
5 measurement for rehabilitation to discipline-
6 specific outcomes to measure is too much
7 speech pathology the right -- I mean, is this
8 too much? Is that too little? Was that right
9 for that patient? Because we haven't
10 standardized as an industry, and this begins
11 to standardize that process. So I don't know
12 if that answers the impact. I think there's
13 twofold for that.

14 CO-CHAIR KNOWLTON: Ramon?

15 MEMBER R. BAUTISTA: So it's the
16 measure's intent to have all patients with
17 strokes undergo speech therapy consult and
18 undergo the FCM? Is that the intent of this
19 measure here?

20 DR. MULLEN: It is not.

21 MEMBER R. BAUTISTA: So how would
22 we know who undergoes FCM?

1 DR. MULLEN: The person who should
2 be scored on the FCM is the person in this
3 case for 0446 would be the person who has a
4 stroke who is treated by speech-language
5 pathology typically for a reading disorder.
6 So that is not the same as saying that we
7 think that all stroke patients should be
8 treated for reading. That is not the intent.

9 CO-CHAIR KNOWLTON: Jocelyn, do
10 you want to add something to this? I see you
11 reaching.

12 MEMBER J. BAUTISTA: So the way I
13 interpret high-impact in terms of what we need
14 to evaluate is what numbers of patients does
15 this measure impact, right? And is that a
16 large number? That's basically what we're
17 being asked to evaluate here, right? So for
18 this measure, this measure will affect roughly
19 15,000 patients a year, those patients who
20 receive pathology services. Am I?

21 DR. PACE: So let me try another
22 way. You're looking at this in relationship

1 to a specific measure. Forget about the
2 specifics of this measure for a moment and the
3 question is this is the one with functional
4 communication measure, reading. So the
5 question is is this a, you know, does it
6 affect a large number of patients? Is it
7 subject to quality issues? Is there high
8 resource use associated with it? Or is it a,
9 you know, high patient and societal
10 consequences to this issue? So you'll get at
11 whether the particular measure is an
12 appropriate way to address this.

13 This is strictly a question of
14 whether this is an area we should have a
15 performance measure at all because of those
16 kinds of things. If there's a lot of people,
17 there's really severe consequences or high
18 resource use, et cetera. You'll get to the
19 specifics of the measure in terms of whether
20 that's the way to go in terms of this area.
21 So this is, you know, at a higher level in
22 terms of is this really even an area that

1 merits us taking a look at and having
2 performance measures.

3 CO-CHAIR KNOWLTON: Do you want to
4 reply to that, Jocelyn?

5 MEMBER J. BAUTISTA: So
6 operationally then are we asking ourselves is
7 stroke a high-impact area, or are we asking
8 ourselves are the numbers of patients treated
9 --

10 DR. PACE: I don't think you can
11 focus it on the number treated because part of
12 the problem may be they're not getting
13 treated. Yes, right.

14 CO-CHAIR KNOWLTON: Jane?

15 MEMBER SULLIVAN: I think -- I
16 understood that we were to look at these
17 measures individually and that this measure is
18 about reading deficits. And it's a subset of
19 all these people who have stroke who have
20 communication deficits who have reading. So
21 it's 16.5 percent based on the data set
22 presented that had -- that were treated for

1 reading dysfunction. So it's a smaller group
2 than stroke or than stroke that has
3 communication problems.

4 DR. PACE: What I was just saying,
5 it's people that have this particular deficit
6 because as you were saying not all stroke
7 patients will have this deficit. What I'm
8 saying is I don't know this data but they're
9 presenting data from their data set on people
10 that they know who have been treated for this.
11 Perhaps there are more stroke patients who
12 actually should be treated for this. I don't
13 know in your field whether that's the case or
14 not, or whether those who are treated is
15 truly, you know, just the number who have this
16 deficit. So it is about strokes and in this
17 case the reading deficit that we're talking
18 about.

19 CO-CHAIR KNOWLTON: Just speaking
20 for myself I'll take that on its face but I
21 would like to acknowledge some agreement with
22 Michael's point that I could do a correlation

1 that says that 75 percent of all stroke
2 patients have brown eyes. You know, it
3 doesn't -- so you could say well that impact
4 is great because it's half of all stroke
5 patients, but there's no relevant
6 intervention, there's no impact there
7 whatsoever because it's not tied to any type
8 of particular outcome.

9 So it does get a bit confusing if
10 you separate the impact because otherwise I
11 guess you're just doing it on numbers, does it
12 affect a lot of people, and we could have all
13 kinds of things that affect a lot of people
14 that are not relevant to a measure that you
15 would want to put.

16 DR. PACE: Exactly, right.

17 CO-CHAIR KNOWLTON: And so I
18 understand your point.

19 DR. PACE: So I think the
20 overarching thing is that this is all in the
21 context of quality of care for the stroke
22 patients and particularly those who have

1 reading deficit. But you're right, I mean,
2 and it's an area that we have had other
3 discussions about trying to clarify or
4 collapse these.

5 CO-CHAIR KNOWLTON: Michael, go
6 ahead. I'll come back to you, I'm sorry.

7 MEMBER KAPLITT: Because I mean I
8 think we're all kind of saying the same thing
9 it's just I guess the question is like in 1a
10 where is the data that says specifically that
11 a reading deficit is a big problem in stroke?
12 I mean, maybe if that's the simplest way to
13 put it, right? Because -- and the reason I
14 say that is because all of this stuff about
15 aphasia appears in many of the other measures.
16 And so if we're going to just take that as the
17 impact then why are we measuring 12 different
18 things here today? You know, why don't we
19 just have one global measure?

20 So that's I guess what we're
21 struggling with trying to look at because if
22 it turns out that it's just 2,000 patients or

1 something then obviously that's not. And if
2 we take it on faith that maybe there's more,
3 you know, well, what's the data?

4 DR. PACE: Right, no, and that's a
5 fair question.

6 MEMBER KAPLITT: And I think
7 that's what we'd like to know. So maybe the
8 developer or somebody can give us more
9 information.

10 DR. MULLEN: One way to put these
11 numbers into context is that the 15,000
12 episodes of care from last year were those
13 reported to our National Outcomes Measurement
14 System. And our best estimate is that
15 approximately 10 percent of eligible speech-
16 language pathologists who are eligible to
17 participate in this system do. And so then I
18 think we could -- we could generally say that
19 the total number of episodes of care of stroke
20 patients receiving speech-language pathology
21 services is somewhere north of 150,000.

22 We just have 10 percent for those.

1 And assuming our data are representative then
2 about 16 and a half percent of those 150,000-
3 plus patients were treated for reading
4 disorders.

5 CO-CHAIR KNOWLTON: Okay.

6 DR. MULLEN: So that would put it
7 more in the neighborhood of twenty-five or
8 thirty thousand.

9 CO-CHAIR KNOWLTON: Helen?

10 DR. BURSTIN: I just want to make
11 one point that it's also not the absolute
12 numbers. And if you look up there it's also
13 severity. So if we limited everything to just
14 the numbers of people you would oftentimes
15 leave out things that are actually quite
16 serious but maybe don't affect a lot of
17 people.

18 So, we did, you know, a fair
19 amount of work a couple of years ago on
20 pediatric heart surgery. Again, not huge
21 numbers, but pretty significant impact for
22 those who do. So I just want to at least put

1 that in context for you.

2 CO-CHAIR KNOWLTON: A.M.?

3 MEMBER BARRETT: Let me comment
4 that the work group struggled with this issue
5 that's being discussed of, you know, the
6 feeling of good faith with the developer that
7 what was being presented could fully help us
8 to be responsible to the larger potential
9 scope of NQF endorsement, right? Beyond the
10 NOMS database.

11 And the guidance we received on
12 the work group call was that for the area of
13 impact we may be able to use our own expert
14 judgment to some extent, and please correct me
15 if I'm incorrect. However, with the other
16 areas like reliability and in particular
17 validity we can drill down much further as the
18 group feels appropriate.

19 CO-CHAIR KNOWLTON: Other comments
20 on impact? Karen?

21 DR. PACE: So, did you get an
22 answer to your question about the reading?

1 MEMBER KAPLITT: Yes, I guess. I
2 mean, what I would really like to see rather
3 than, you know, the percent of patients that
4 were treated is some data from studies that
5 say what the scope of the problem is, this
6 specific problem.

7 You know, are there studies that
8 say that you know, 10 percent of all stroke
9 patients let's say have specific reading
10 problems where this outcome measure is
11 actually going to make a big impact, you know?
12 That's really not here. That would be nice,
13 and that would be nice for all the other
14 things. I don't get the sense we're going to
15 get that today but that's sort of what I'm
16 driving at I think.

17 CO-CHAIR KNOWLTON: Ramon?

18 MEMBER R. BAUTISTA: Is there data
19 -- for the speech people in the group, is
20 there data that shows that an improvement of
21 one point or one level in the FCM can happen
22 without any rehab? In other words, can this

1 be a natural course of getting better after a
2 stroke? I mean, I don't know the answer to
3 that. I ask the speech therapists here. Do
4 we actually need an intervention for this or
5 would this happen as a matter of natural
6 course?

7 CO-CHAIR KNOWLTON: Mary, do you
8 want to take a shot?

9 MEMBER VAN DE KAMP: You're asking
10 the million dollar question. I think that
11 that is a challenge in any sort of
12 rehabilitation to determine if you didn't
13 intervene what would the result be. But to
14 take the chance of not intervention, you know,
15 I think CMS asked that question in payment.
16 You know, if you just left a person to
17 rehabilitate or improve how much is just going
18 to naturally happen with this.

19 I think that's one of the reasons
20 we can look at outcomes. That's one of the
21 reasons by having an outcome we can start to
22 drill back and look at are those the -- what

1 are the reasons that it doesn't improve and
2 can we compare. But if what we struggled with
3 in the rehab industry is any sort of benchmark
4 that we would all standardize across each
5 other's provision of services to begin to look
6 at what happened. So I think if we had an
7 outcome to say 80 percent of the patients who
8 had reading issues were treated and improved
9 this much we would have a measurement to
10 decide how they improved that much. Right now
11 without that we can't answer some of those
12 questions that will talk to what Karen said is
13 resource utilization. Because that's one of
14 the things that's looked at. So a long-winded
15 answer to your question. It's a very
16 difficult one.

17 CO-CHAIR KNOWLTON: Going back --
18 continue.

19 MEMBER R. BAUTISTA: It would
20 sound like a placebo-controlled trial would be
21 a more reasonable thing to do rather than
22 having a national measure to require everybody

1 to do this with no end in sight. I mean, just
2 my opinion.

3 DR. MULLEN: This is Rob. There
4 does seem to be some indication from our data
5 that there is certainly a possibility that
6 some patients will make a level of progress in
7 the absence -- we don't have data on patients
8 who receive no services, but we certainly do
9 have data on patients who receive very little
10 service, you know, less than an hour in some
11 cases and some of them do make progress.

12 What the data from the National
13 Outcomes Measurement System shows is that the
14 likelihood of making progress is very strongly
15 related to how much treatment they receive.
16 So there will be some. I think it's probably
17 safe to assume that there will be some who
18 would make progress in the absence of any
19 treatment.

20 CO-CHAIR KNOWLTON: Therese?

21 DR. MULLEN: The treatment
22 certainly increases based on the -- increases

1 the likelihood of making that progress.

2 CO-CHAIR KNOWLTON: Go ahead,
3 Therese.

4 MEMBER RICHMOND: Two issues, and
5 this is all in this section. One is I agree,
6 they did not -- you don't really see evidence
7 that reading -- I would have been convinced if
8 we saw this number of people have reading,
9 this is the impact on life. People then are
10 functionally much more impaired in terms of
11 the ability to, you know, carry out normal
12 life activities. So I didn't see that.

13 And the second thing, and this may
14 be jumping ahead, is I'm not convinced and I
15 don't want to -- I'm not a speech-language
16 pathologist. However, I feel like I'm looking
17 at a 2 by 2 table here that's missing half the
18 table in that we're shown that hours of
19 intervention that we -- the percent goes up,
20 you have an increased percentage of people who
21 improve. However, you know, time is a factor
22 here that's not really controlled for.

1 So we're only seeing people who
2 are treated, who have an intervention and they
3 progress, but since those interventions happen
4 over time we really don't know whether the
5 intervention is linked to that outcome or the
6 person would have improved just by virtue of
7 time. And I don't see any evidence here that
8 shows linking that structure-process outcome.

9 CO-CHAIR KNOWLTON: Other? Jane?

10 MEMBER SULLIVAN: As a rehab
11 therapist I share Mary's sense of, you know,
12 this is a first step in trying to standardize
13 what we do and standardize the way we look at
14 what we do and get some answers.

15 I guess one of the things that is
16 troubling to me is the percent of clinicians
17 that would be eligible to report on this
18 measure. And as I understand it, only 10
19 percent of eligible speech-language
20 pathologists have done the training to do this
21 -- these measures. So you know, it's further
22 a small -- in terms of impact it's a smaller

1 percentage of clinicians and therefore a
2 smaller percentage of patients that it
3 affects. And I know you want to think about
4 driving practice in a good way but in terms of
5 impact that gets smaller and smaller.

6 DR. MULLEN: Well, I would suggest
7 it's sort of a catch-22 situation in that with
8 NQF -- with continued NQF endorsement that
9 would be important and stimulating increased
10 participation.

11 CO-CHAIR KNOWLTON: Karen?

12 DR. PACE: Right. So I think
13 these are all important questions and I guess
14 I think some of these apply to other criteria
15 and so maybe you want to talk about impact.
16 But the question about the relationship to
17 treatment is what we would talk about under
18 evidence.

19 And you know, for outcome measures
20 we don't ask them to submit all the bodies of
21 evidence but to provide a reasonable rationale
22 that there are interventions or treatments or

1 services that do impact that, and that's
2 certainly up for your discussion of whether
3 you think, you know, there really is any
4 impact.

5 But you know, perhaps -- and then
6 certainly how many people are using the
7 measure, you know, under usability that would
8 be great. And I think it is, you know, it's
9 not a requirement for NQF endorsement that
10 people are already using it though this is
11 coming back for endorsement maintenance. So
12 it's certainly a fair question to ask when we
13 get to usability in terms of, you know, why
14 isn't it being used more and what are the
15 plans to really get it into public reporting.
16 So these are all important questions but you
17 may want to kind of move through.

18 CO-CHAIR KNOWLTON: On impact.
19 Michael?

20 MEMBER KAPLITT: I mean, the last
21 statement from the developer concerned me
22 because I -- you know, we're not an NIH study

1 section here and we're not a, you know, a
2 foundation. We're here to have a different
3 purpose is my understanding which is not to
4 figure out the potential of this to do things
5 or whatever, but is there enough evidence to
6 say that people should be measured by this
7 standard now.

8 And that's where I think the
9 impact question is coming in here, that is
10 there -- have we been provided with enough
11 data to say that this specific measure, that
12 there's enough evidence to say that we should
13 now endorse this or maintain the endorsement,
14 that this is where all of you guys should be
15 measured by. It's not a matter of whether
16 this is important or whether there's the
17 potential or some people could benefit, you
18 know. And that's my concern here is are we,
19 you know, do we have that.

20 DR. PACE: Right. So your
21 question is very specific about -- and which
22 is brought up about the numbers of people, the

1 consequence of the reading deficit, et cetera,
2 and that's exactly what you should be focused
3 on right now.

4 CO-CHAIR KNOWLTON: Therese, is
5 your hand still up? Okay. Any other
6 comments? We're voting on impact. Open the
7 voting, please.

8 MS. THEBERGE: Four high, eight
9 moderate, four low, five insufficient
10 evidence.

11 CO-CHAIR KNOWLTON: Okay. I
12 understand that Mary's stepping in for Raj.
13 He had to leave to get his flight. And we're
14 onto evidence. Is there sufficient evidence,
15 importance of the measure evidence, yes or no.
16 Up to you, Mary.

17 MEMBER VAN DE KAMP: I think as we
18 go back to what Karen was saying the evidence
19 is not as significant a requirement within the
20 outcome process. And so as we talked about is
21 there evidence of this being a risk within
22 this measure we all agreed, those of us who

1 voted.

2 CO-CHAIR KNOWLTON: Questions?
3 Comments on evidence?

4 CO-CHAIR TIRSCHWELL: I just
5 wonder, I'm recalling back to the, you know,
6 assess for rehab measures that we approved the
7 other day. They quoted thousands of studies
8 supposedly showing that rehab had benefit and
9 at least some of them must have included
10 assessment of some of these speech and
11 language pathology services. So, I am not a
12 master of that literature but it would seem to
13 me that there must be some evidence that
14 interventions along these lines which we
15 haven't talked about yet exist.

16 MEMBER VAN DE KAMP: Rob, do you
17 have something? I don't have -- I have -- the
18 details on mine was what was presented to the
19 work group, but I don't have -- do you have --

20 MEMBER BARRETT: Well, I'm just
21 going to comment again that we were directed
22 that for the number one criteria we don't have

1 to be dependent on just information that is
2 presented by the developer. And so indeed I
3 would confirm that the fact that good practice
4 standards exist requiring reading and other
5 speech-language pathology treatments in most
6 high-quality settings would see -- of
7 evidence. Although that wasn't made in the
8 application.

9 CO-CHAIR KNOWLTON: Anything else
10 on evidence? Karen, is your hand up?

11 DR. PACE: So, would you put up 1c
12 on the -- so you can see what they presented?
13 So this is the area with the health outcome.
14 Is there a relationship to the, you know,
15 structures, processes, services. And that
16 certainly is something that you can discuss.

17 And I think they used as a proxy
18 the relationship between treatment service.
19 We only look at section 1c.1. Okay. So go
20 down to the next page is where they provided
21 that information. And that's I think what
22 some people were questioning earlier but this

1 is the place to bring that question up.

2 CO-CHAIR KNOWLTON: Therese?

3 MEMBER RICHMOND: -- my earlier
4 point is I don't think that this is convincing
5 evidence of linking the process of care to the
6 outcome measurement. I think we're seeing
7 only people who were treated with hours of
8 treatment, but there's -- I would like to have
9 seen at least evidence from the literature
10 linking interventions of speech pathology with
11 improved outcomes. So I don't believe that
12 evidence was shown or I'm not seeing it.

13 CO-CHAIR KNOWLTON: Other
14 comments? Okay --

15 MEMBER BARRETT: I would just say
16 the work group agreed.

17 CO-CHAIR KNOWLTON: On the issue
18 of evidence let's vote. Oh, Mary had a point.
19 I'm sorry, I didn't see it.

20 MEMBER VAN DE KAMP: I think the
21 question that we have is that we didn't have
22 to demonstrate the evidence within this. We

1 could use our, you know, our research for our
2 disciplines and per the group on the panel
3 that was mixed, not just speech-language
4 pathologists. But I think is that -- are we
5 voting on -- and I guess I'm still confused
6 because I know Karen was great because we
7 tried to really get into this on our work
8 group. We struggled with this one a little
9 bit being that it was an outcome measure and
10 not a process measure and where that
11 definition was. So to Karen.

12 DR. PACE: So, what we're asking
13 and you know, what we like to see here is for
14 the developer to identify the relationship
15 between at least one service intervention,
16 health care structure that impacts this
17 outcome. So, sometimes we'll see, for example
18 on the readmission measure some discussion
19 that transition practices, discharge status,
20 coordination of care, getting the patient to
21 their right next provider are things that
22 impact readmission and there is, you know, we

1 don't ask them to go through the same, you
2 know, description of the body of evidence as
3 you saw yesterday for process measures.

4 So, this developer is noting that
5 speech pathology treatment is related to
6 making progress. You know, that's still open
7 for you to decide whether that is sufficient
8 rationale for the measure. I'm just saying
9 that we didn't ask the developer to submit,
10 you know, a summary of the body of evidence
11 like we require for the process measures.

12 CO-CHAIR KNOWLTON: Jane.

13 MEMBER SULLIVAN: I think one of
14 the large points of discussion on the work
15 group call is the fact that this is a
16 maintenance measure and there's been some time
17 since the measure was first endorsed. The
18 work group was looking for some data that
19 would show that using this measure has had
20 some impact, that you know, more than what was
21 perhaps submitted the first time. And we had
22 hoped and thought that the developer was going

1 to provide that for us. And I'm not seeing
2 that.

3 CO-CHAIR KNOWLTON: Anything else?
4 Okay, now we can vote on evidence.

5 MS. THEBERGE: Five yes, sixteen
6 no.

7 CO-CHAIR KNOWLTON: Okay, so this
8 measure does not get approved for -- re-
9 approved I guess.

10 We now will go into usual order
11 and will be up to 0442. And David, you're
12 going to do this?

13 CO-CHAIR TIRSCHWELL: Okay, so
14 Jane, is this one that you presented?

15 MEMBER SULLIVAN: Yes, this one's
16 mine.

17 CO-CHAIR TIRSCHWELL: And I guess
18 to some degree we need to reflect on what just
19 happened.

20 MEMBER SULLIVAN: I think there's
21 going to be similarities throughout this
22 measure. Just one point of clarification. In

1 terms of the scoring on the document that you
2 received there were three people on the work
3 group call but the numbers are four. I was
4 credited for two votes. I don't know if
5 that's because I'm from Chicago.

6 (Laughter)

7 MEMBER SULLIVAN: There were only
8 three people. I'm not sure what's most
9 helpful. I think that the conversation that
10 we had on the last measure is going to be very
11 much like this one. I think the difference is
12 as I look numerator statements, very similar
13 denominator statements, similar with respect
14 in this regard to writing. People who are
15 using an augmentative alternate communication
16 system are excluded from this measure.

17 If we go down to impact the -- we
18 have the same kind of data. In this case the
19 developer talked about 10 percent of the
20 subset of people who were being seen for
21 speech-language services were receiving
22 services for a writing disorder. And that was

1 the extent of the impact data that we had to
2 evaluate.

3 CO-CHAIR TIRSCHWELL: Any further
4 comments on impact? Let's go ahead and open
5 the voting for impact.

6 MS. THEBERGE: Four high, seven
7 moderate, eight low, two insufficient
8 evidence.

9 CO-CHAIR TIRSCHWELL: So we
10 proceed. Is there evidence. Jane?

11 MEMBER SULLIVAN: I think the
12 findings here that were presented by the
13 developer are consistent with what we talked
14 about in the last measure. There was some
15 information that time of intervention, hours
16 of care does affect outcome but that was
17 pretty much the extent of it.

18 CO-CHAIR TIRSCHWELL: Right. And
19 -- yes. Any further comments or questions or
20 points of differentiating this measure from
21 the previous one?

22 DR. MULLEN: As the developer if I

1 could just say that I think that there is no
2 cause to differentiate the evidence -- here or
3 any of the ones for the remaining measures
4 from the one that was just addressed. So I
5 guess, I don't know if it would be some sort
6 of violation of NQF protocols but if the
7 previous measure will not be moving forward
8 because of the evidence criterion, it's not
9 going to be any different for this or the
10 remaining measures. So I don't know if
11 there's some way to speed up the process so no
12 one's time is wasted with individual
13 deliberations of the remaining measures.
14 Because the evidence sections are approached
15 in the same way across these measures.

16 CO-CHAIR TIRSCHWELL: Thank you
17 very much for that comment. Karen, did you
18 have something to say?

19 DR. PACE: I think before -- I
20 just want to bring out this question to the
21 committee and also to the developer. You
22 chose to present it this way in hours of

1 treatment, but those of you in the field, are
2 there -- is there evidence of specific speech-
3 language treatments that do impact this
4 outcome? So, you know.

5 MEMBER VAN DE KAMP: I guess I'm
6 going to go back. I'm sounding a bit like a
7 broken record, but we do use it for that
8 purpose. But it's just like the FIM scoring
9 which was used in the stroke study. They
10 measured what the FIM change was and then they
11 went back to find out what was the procedures
12 within that change where they had a greater
13 change. Were there different procedures used
14 to better determine the best practice of that
15 care? And so that's how we used that within
16 our company. But that's a different -- that's
17 not publicly --

18 DR. PACE: Right, I understand
19 that's how you used any outcome measure --

20 MEMBER VAN DE KAMP: Right.

21 DR. PACE: -- in terms of
22 determining how to improve. But often

1 generally there is some evidence to start with
2 of even giving speech-language pathology
3 treatment. Is there some studies that
4 indicate that certain types of interventions
5 actually impact patients?

6 CO-CHAIR TIRSCHWELL: A.M.?

7 MEMBER BARRETT: Mary, you can
8 fill in, but certainly one of the professional
9 societies, the Association for Neurogenic
10 Communication Disorders, has an evidence-based
11 treatment set of work groups and practice
12 guidelines and consensus statements along
13 those lines.

14 MEMBER VAN DE KAMP: As does
15 American Speech and Hearing. There's a number
16 of evidence. And I think if you're -- I mean,
17 I wasn't expecting to have to justify the
18 profession of speech and language pathology.

19 (Laughter)

20 MEMBER VAN DE KAMP: Because I've
21 given my career to this whole thing. At this
22 point I think it was well done, but you know.

1 I think to your point as Rob is
2 saying that if the evidence is something that
3 doesn't meet NQF's requirements to be
4 demonstrated then that's something different
5 than if the evidence supports whether, you
6 know, these services are valuable or not.

7 And so personally I struggle with
8 our inability to start put forth outcomes. We
9 get caught up in process so frequently that
10 we're almost afraid to judge ourselves by an
11 outcome. And so I want to make sure we don't
12 --

13 DR. PACE: And that's why -- I
14 mean before we go down this road I really want
15 -- I think we need to have a discussion about
16 this. Because the NQF is really interested in
17 outcomes. Function, health status, it is a
18 huge driving force. Outcomes are integrative
19 of a lot of different care processes and
20 interventions so they're much more efficient
21 than, you know, trying to parse out 20 steps
22 in a process. And we do not require that the

1 quantity, quality and consistency of a body of
2 evidence be demonstrated for an outcome
3 measure, but that there's some reasonable
4 relationship to services, health care services
5 that are impacting that outcome.

6 I guess I would think that because
7 we have this whole treatment that is valid
8 enough to refer patients to and to get payment
9 for that there must be some relationship
10 between getting speech-language pathology
11 services and these outcomes. So I just want
12 to try to understand what --

13 CO-CHAIR TIRSCHWELL: So, can I
14 interrupt for one second?

15 DR. PACE: Yes.

16 CO-CHAIR TIRSCHWELL: Let me let
17 Jordan and Salina talk first.

18 MEMBER EISENSTOCK: So just as a
19 member of the work group I definitely agree
20 that all these measures, this is going to be
21 the sticking point for each of them. And I
22 think it comes down to what Ramon and Therese

1 were saying which I completely agree with is
2 how to interpret that half of a 2 by 2
3 situation. And Ramon's point that it doesn't
4 really give us any information or we don't
5 know from any of the data we were able to see
6 what is the natural progression of recovery
7 versus what was the impact from these
8 particular treatments.

9 I would say that it makes it even
10 more complicated and because there's a chance
11 that we might not get to the measure that I
12 was going to lead, the 0448, in that
13 particular one about memory, and I don't know
14 how we rationalize this or put it all
15 together, 4 hours of treatment had a higher
16 percent making progress than 5-plus hours of
17 treatment. So I think there is some real
18 problems with using this as our NQF-based
19 evidence in that respect. That didn't make
20 much sense.

21 CO-CHAIR TIRSCHWELL: So, I guess
22 -- and I think you were trying to make this

1 clarification, Karen. Does the evidence that
2 we're demanding here to get endorsement, does
3 it have to be that we're showing that this
4 measure, there's evidence that this measure
5 itself is driving improvement in outcomes, or
6 do we -- is the evidence that what this
7 measure is addressing which is speech
8 pathology services, is there evidence that
9 that improves outcomes. And if that which is
10 not based on what's here, if that exists then
11 that's sufficient evidence to move forward.
12 Is it the latter?

13 So they're saying it's the latter.
14 So which seems a little contrary to the vote
15 we had on the first one so I take comments.
16 Jocelyn?

17 MEMBER J. BAUTISTA: And isn't it
18 still the responsibility of the developer to
19 present that evidence to us? And not for us
20 to do the literature search to find that
21 evidence?

22 DR. PACE: Right. So this is, you

1 know, that's what I'm saying. We are not
2 requiring for health outcomes, function being
3 a prime example, that they present a
4 literature review, a body of evidence like we
5 are requiring for process measures. The
6 reason being is that there are multiple
7 processes and interventions that affect these
8 outcomes, not just speech-language but other
9 things that are going on for the patient
10 probably in their initial treatment of the
11 stroke impacts some of these outcomes.

12 So, we are just saying is there
13 reasonable expectation that health care
14 services -- is there rationale that health
15 care services, in this case speech-language
16 pathology, affects this particular outcome.

17 CO-CHAIR TIRSCHWELL: And even
18 more did they give us that reasonable
19 expectation in the document --

20 DR. PACE: Right.

21 CO-CHAIR TIRSCHWELL: -- that they
22 sent to us. And I guess maybe that's --

1 DR. PACE: Right.

2 CO-CHAIR TIRSCHWELL: -- the piece
3 that's missing in all of these.

4 DR. PACE: And so, you know, I
5 understand what you all are saying about what
6 was presented. And you know, one approach
7 would be if you consider this all insufficient
8 we can put these on the back-burner and
9 continue the work with the developer for a
10 future submission where they can --

11 CO-CHAIR TIRSCHWELL: Okay.
12 Jolynn?

13 MEMBER SUKO: I was just going to
14 say unlike the readmission measures which
15 were, you know, driving some interventions, we
16 don't even see interventions of a hypothesis.
17 I mean, you know, we didn't even have
18 reasonable hypothesis about what's driving
19 these based upon what's been submitted. And
20 these have been endorsed for 4 years now, you
21 know, unlike the others. And so I'm just
22 struggling with where we are in terms of our

1 measure maturation.

2 CO-CHAIR TIRSCHWELL: Bill?

3 MEMBER BARSAN: Yes, I'm just -- I
4 guess I'm not really clear this is really an
5 outcome. I mean, I don't know, it's just,
6 it's not clear to me whether this is really
7 more of a process rather than an outcome. I'm
8 just not -- I mean I understand somebody who's
9 alive or dead, that's -- I mean I can separate
10 that and say that's an outcome.

11 (Laughter)

12 MEMBER BARSAN: One way or the
13 other, readmission --

14 CO-CHAIR TIRSCHWELL: That's an ED
15 doc talking.

16 (Laughter)

17 MEMBER BARSAN: No, no, seriously.
18 But I'm not sure what the outcome is.

19 CO-CHAIR TIRSCHWELL: Improvement.

20 DR. PACE: It's function and it's
21 improvement. It's not just one point in time,
22 it's a change in function and those are

1 considered outcome measures. We have other --
2 in other settings we have percent improved in
3 their ADLs, different ADLs as an outcome
4 measure. Those need to be risk-adjusted. So
5 this is, you know, function. These are always
6 more difficult, granted that, but we would
7 classify change in function as an outcome.

8 CO-CHAIR TIRSCHWELL: Michael?

9 MEMBER KAPLITT: Don't you need
10 some evidence that it actually makes a
11 difference? Right? I mean, isn't that what
12 we're debating here? We get the point. And
13 your point which is look, you know, we could
14 all get caught up in specific interventions.

15 I for one am a huge believer, so
16 that nobody's offended, I'm a huge believer in
17 these services, but there's a difference
18 between saying that we inherently believe that
19 they have value and has the level of evidence
20 risen -- has it risen to a level that we're
21 going to hold people to a standard which is
22 what we're talking about I think, unless I'm

1 misunderstanding what we're doing here.

2 MEMBER BARRETT: I think I can see
3 where we're all going here and I think that
4 the work group was quite sympathetic to this
5 direction. As we continue potentially down
6 this road I think the work group would
7 probably want to make a couple of comments
8 that modality-specific measures as was said
9 before, outcome measures have been really
10 important to develop and Cramer and a number
11 of other people have written about this. It's
12 to improve the validity of stroke care.

13 Discipline-specific measures are
14 really important and in particular here we've
15 talked -- yesterday I think when we talked
16 about dysphagia looking at a process that is
17 already endorsed and has value. So before we
18 leave this topic which it sounds like we're
19 moving toward we want to make those comments.

20 CO-CHAIR TIRSCHWELL: Gail?

21 MEMBER COONEY: I just worry that
22 the developer was perhaps misled by some of

1 our verbiage that basically says if you're an
2 outcome measure you don't need to demonstrate
3 evidence. And I would hate to see us throw
4 this out with that kind of misunderstanding.

5 CO-CHAIR TIRSCHWELL: Jane?

6 MEMBER SULLIVAN: I want to go
7 back to our work group call and we really
8 struggled with this. And I think A.M.
9 mentioned that one of the pieces of guidance
10 we were given was that evidence was not only
11 what was written but what was clinical
12 judgment. And that's vague. But I also think
13 in terms of the developer the work group
14 really asked for more information about what's
15 happened since the time that this measure was
16 first endorsed and now. And I'm not seeing
17 that we received significant information to
18 further inform our decisions.

19 CO-CHAIR TIRSCHWELL: Therese, did
20 you have a comment?

21 MEMBER RICHMOND: Yes, and I
22 understand that we don't need to look at the

1 evidence like a process measure, but I was on
2 the outcome measures that we talked about all
3 morning so I get it.

4 (Laughter)

5 MEMBER RICHMOND: I learned a lot.
6 However, I do think that it was inherent to
7 provide the linkage between structure, process
8 and outcome or one of those, and that is what
9 I believe is missing. So, you know, if -- and
10 I don't know the literatures, but I didn't see
11 the convincing evidence that that linkage was
12 made.

13 CO-CHAIR TIRSCHWELL: Karen, do
14 you have one final comment or you're good?
15 Well, I guess I would suggest that we vote one
16 more time on the evidence and then depending
17 on the outcome we'll decide what we do with
18 the other measures. So can we go ahead and
19 open up the voting for the evidence for this
20 measure?

21 MS. THEBERGE: Three yes, eighteen
22 no.

1 CO-CHAIR TIRSCHWELL: So I guess
2 at this point I would open the floor to the
3 NQF people. It seems like the measure
4 developer, maybe we should check back in,
5 agrees that they're all very similar in this
6 exact regard and would likely receive the same
7 evaluation. So can we somewhat
8 administratively apply the same ruling to the
9 other measures?

10 DR. MULLEN: The measure developer
11 still feels that way.

12 DR. BURSTIN: Yes, and this is
13 Helen.

14 CO-CHAIR TIRSCHWELL: Thank you.

15 DR. BURSTIN: I think that's quite
16 doable. I do think it's important to look at
17 the list of all of them though and see if
18 there are some in fact where that may not be
19 the case. I mean again, just sitting here
20 trying to read some of the systematic evidence
21 reviews. I'm an internist, not a rehab
22 person. It certainly looks like some of the

1 issues around swallowing and aphasia might
2 have more evidence than some of the others do.

3 Again, I think we're still limited
4 by what's in the submission form clearly. So
5 I think it's fine to do, but if anybody wants
6 to just as a process point pull out any other
7 measures for further discussion. Otherwise I
8 think it's fine to proceed.

9 CO-CHAIR TIRSCHWELL: So for the -
10 - do you want to save an application --

11 DR. BURSTIN: And have details.

12 CO-CHAIR TIRSCHWELL: -- before we
13 triage it so to speak?

14 DR. BURSTIN: Yes.

15 CO-CHAIR TIRSCHWELL: Anybody want
16 to chime in? Mary.

17 MEMBER VAN DE KAMP: I guess the
18 only thing I really want to state for public
19 record is that we have to continue to move
20 down the road of outcomes. And I think it is
21 a difficult philosophical discussion in
22 medicine and in rehabilitation, and that I

1 think is one of the reasons that people have
2 been hesitant to develop these.

3 And if you look historically at
4 what the government and CMS looks at is
5 they're looking for some more standardized
6 assessment of the care that we provide. And
7 I agree that this application may, you know,
8 the evidence certainly could be -- we could
9 look at broader-based. I mean, we talked very
10 clearly that the assessment of rehabilitation
11 was absolutely critical and we talked about
12 ordering was critical.

13 Now, okay, we ordered and assessed
14 it but now we're talking about what was really
15 delivered and we have hesitancy to determine
16 if there's an outcome associated with that.
17 And I've seen that over and over again.
18 Everyone's more comfortable with process
19 measures than they are to put the name on the
20 bottom line to say I stand behind that the
21 services I provided changed function. And
22 that's really what these outcomes are

1 determined to do. I provide --

2 To your point, I wanted to --
3 Jordan, to say that's a good statistic that if
4 I gave more than on average 5 and a half hours
5 I didn't get any better than that. But we
6 don't have those kind of measurements. So we
7 think more is better in health care sometimes,
8 so without that measurement.

9 So I realize that I'm sort of
10 having this little, you know, a bit of a
11 soapbox here but I'm concerned that we don't
12 take this off the table and more comfortably
13 look at well, I did the right process but did
14 it have the right outcome. And that's where
15 I struggle with approving hands down
16 assessment is great yesterday, but do we ask
17 for a lot of basis for why the assessment was
18 so important? And why we ordered? And yet we
19 look at okay, well once we did that then
20 what's the value.

21 So I understand that you have
22 hesitancy but I just want to be sure that we

1 don't look beyond the baby steps that we need
2 to do and grow. From the speech pathology
3 side the recognition that we -- why is it only
4 10 percent? Because no one's forced our
5 industry to step forward to defend through
6 some sort of objective measurement to say what
7 we're doing. And so that's all.

8 CO-CHAIR TIRSCHWELL: Thank you,
9 Mary. Salina?

10 MEMBER WADDY: So I don't think
11 any of us as stroke neurologists or
12 practitioners would argue that we will not
13 send our patients for these services. I think
14 the challenge is that we're being asked to
15 vote on evidence that we are not being
16 provided, and we aren't sure of the evidence
17 because that's not necessarily our field in
18 terms of how critically significant the
19 evidence is.

20 So I'm not clear whether or not
21 it's just that we don't have the evidence for
22 this presentation or if we in general within

1 health care there's no evidence.

2 CO-CHAIR TIRSCHWELL: Okay.

3 Risha.

4 MEMBER GIDWANI: I may be a little
5 confused here, but it seems to me that there
6 are a few different issues floating around,
7 one being the standardization, another
8 potentially being uptake, another being
9 measurement and communication of results as a
10 result of this measure. And I wonder if the
11 fact that this is being endorsed -- I'm sorry,
12 being maintained, it's already been endorsed,
13 shouldn't that already point to the
14 standardization and the need for the
15 evaluation?

16 If we're putting this measure
17 forth as a means of standardizing the approach
18 I wonder if, (a) has this already been done
19 because it's been in effect for so many years,
20 and (b) if the goal is standardization is this
21 really the appropriate measure to do that, or
22 would another measure that talks about use of

1 a singular tool across a variety of patients
2 accomplish that.

3 CO-CHAIR TIRSCHWELL: Okay, thank
4 you. Michael?

5 MEMBER KAPLITT: Just to reassure
6 you because I think everybody here agrees with
7 what you're saying. But I think there is a
8 distinction though between the assessment and
9 what we're doing here. Because the value of
10 the assessment when you say well, you know,
11 why assess something and then not -- is that
12 if we endorse what we think is a valid
13 assessment tool by enforcing that, by making
14 that a standard that's exactly how we're going
15 to generate the data that will then allow us
16 to determine over time what the appropriate
17 outcome measures should be. So I think there
18 can be a distinction that there can be real
19 value in validating an assessment and sort of
20 trying to encourage that. But I think the
21 outcome measure standard has to rise to a
22 different level.

1 MEMBER VAN DE KAMP: I agree,
2 although I don't think that the -- if I'm
3 mistaken, I may be mistaken that we didn't
4 have a tool. It still relies on the
5 clinician's judgment. So I get a speech and
6 language order and I use the tools that I feel
7 are most valid. So I think it's the same
8 thing in treatment, it's just that it's harder
9 in looking at health outcomes I think to
10 standardize. So I agree, I understand where
11 we are, I just felt for public record it's
12 important that we move forward with trying to
13 progress this.

14 CO-CHAIR TIRSCHWELL: And I
15 personally would encourage you not to take
16 this result as an indication that you
17 shouldn't press on with all due effort.

18 Any other comments before I guess
19 we administratively not endorse. Okay? So
20 then any comments from the developers or --
21 let's start with developers first.

22 DR. MULLEN: No comment.

1 CO-CHAIR TIRSCHWELL: Thank you.

2 And then could we have the operator open up
3 the lines for public comment?

4 OPERATOR: At this time I would
5 like to remind everyone in order to ask a
6 question press * then the number 1 on your
7 telephone keypad. At this time there are no
8 questions.

9 CO-CHAIR TIRSCHWELL: Okay. Any
10 comments?

11 DR. BURSTIN: This is our public
12 comment period for the morning.

13 MS. TONN: My name is Sarah Tonn
14 and the American Academy of Neurology thanks
15 you for the opportunity to comment for the
16 public record.

17 The AAN is a medical specialty
18 society representing 25,000 neurologists and
19 neuroscience professionals who have a major
20 stake in providing the highest quality of
21 patient-centered care for stroke which is a
22 neurologic disease.

1 For the three specific measures
2 addressing in-hospital and 30-day outcome
3 measures which are NQF numbers 0467, 2026 and
4 2027 the evidence, validity and usability
5 criteria have been endorsed based on rigor of
6 statistical models, yet the models are only as
7 good as the data collected. Administrative
8 data is billing data, it is not data that
9 measures quality of care. The data we need to
10 account for stroke severity, stroke --
11 transfer issues, patient-centered preference
12 sensitivities, decision-making on comfort
13 care, socioeconomic status and race are
14 missing. For readmissions for stroke care
15 transitions are a huge piece that are not
16 addressed in the model.

17 The AAN strongly opposes the use
18 of these three measures for public reporting
19 or for use in accountability programs.
20 Endorsement leads to use of these measures in
21 public reporting such as HospitalCompare and
22 this is a disservice to the public as rankings

1 classified by one vendor method can show
2 higher than expected mortality and lower than
3 expected mortality when classified by one or
4 another method.

5 A publication by David Shahian and
6 colleagues and they run the thoracic surgery
7 registry, they wrote in the New England
8 Journal of Medicine in 2010 an article on the
9 variability in the measurement of hospital-
10 wide mortality rates comparing vendor
11 methodologies across four vendors.

12 Each of the four vendors were
13 given the same data. They were given 2.5
14 million discharges in 83 Massachusetts
15 hospitals over a 3-year period. All these
16 vendors were given that same data. Four
17 vendors, UHC which is University Health
18 Consortium, 3M, Thompson Reuters, Foster which
19 is out of Imperial College London, when
20 comparing vendor methods the findings were
21 that a total of 12 of 28, a little less than
22 half that had higher than -- of 12 of 28

1 hospitals had higher than expected mortality
2 rates when classified by one method, and yet
3 had lower than expected mortality when
4 classified by one or more of the other
5 methods.

6 Addressing one more point in
7 particular also supports the AAN's strong
8 opposition to endorsement of these three
9 outcome measures. The strongest predictor of
10 short-term outcomes among stroke patients is
11 baseline stroke severity.

12 The baseline NIHSS or National
13 Institute of Health Stroke Scale score has
14 more predictive power than all other baseline
15 variables, demographics, comorbidities, et
16 cetera, combined. Therefore, evaluating
17 short-term outcomes without adjusting for
18 baseline stroke severity will always be
19 subject to missing variable bias.

20 Smith and colleagues in the
21 Circulation 2009 publication demonstrated in
22 prediction of in-hospital mortality in

1 ischemic stroke using data from Get With the
2 Guidelines that using NIHSS alone produced a
3 C statistic of 0.83. Imagine if all the C
4 statistics reported today in the models
5 adjusting for less important factors has this
6 impact realized the missed opportunity by not
7 adjusting for stroke severity.

8 More scientifically sound and
9 rigorous approach would be to collect the
10 needed data and subsequently use it to adjust
11 and validate the in-hospital and 30-day
12 outcome measures. If the appropriate data is
13 not collected and compared to the in-hospital
14 and 30-day outcome quality measures then it
15 will be impossible to accurately assess
16 quality of care and likely will significantly
17 penalize the tertiary care centers.

18 The AAN's opposition is expressed
19 in the AAN 2010 letter to CMS included in your
20 steering committee materials. Thank you.

21 CO-CHAIR TIRSCHWELL: Thank you
22 very much. Any other comments? No. Okay.

1 Let's see. What is next on our agenda?
2 Lunch. And then what's left for this
3 afternoon, can you guys review with us? Just
4 the related and competing measure evaluations.

5 DR. PACE: Are you caught up on
6 time now?

7 CO-CHAIR TIRSCHWELL: Well, we're
8 half an hour behind. So why don't we take a
9 20-minute lunch, a little bit short, try to
10 reconvene at 12:50 and maybe we can get it all
11 done.

12 (Whereupon, the foregoing matter
13 went off the record at 12:31 p.m. and resumed
14 at 12:53 p.m.)

15 CO-CHAIR TIRSCHWELL: Okay, we're
16 going to get started again and Karen's going
17 to give us an introduction to what we need to
18 do with the next phase here.

19 MS. JOHNSON: And Suzanne is
20 bringing up our slides. We talked about this
21 a little bit yesterday afternoon. I gave you
22 the birds' eye view. Today we're going to go

1 through a little bit more detail about the
2 related and competing.

3 Okay, just to remind you NQF does
4 ask you to consider issues of related and
5 competing measures. So if a measure meets the
6 four criteria which that's what you've done in
7 your meeting so far and there are endorsed or
8 new measures that are related. So related we
9 define as having the same measure focus or the
10 same target population, or if there are
11 competing measures which we define as having
12 the same measure focus and the same target
13 population then we ask you to compare them to
14 address harmonization or selection of the best
15 measure.

16 So if you are looking at related
17 measures we want you to evaluate whether the
18 measures are harmonized, and by that we mean
19 aligned as much as possible in terms of their
20 specifications, or if they're not are the
21 differences justified.

22 For competing measures we ask you

1 to compare and if possible choose a superior
2 measure. And if you can't choose a superior
3 measure then put forward some reasons why
4 multiple measures would be justified.

5 Okay, and pretty much this is in
6 chart form what we just said. So again, what
7 you are thinking about here in terms of
8 competing versus related is how the numerators
9 and denominators basically match up.

10 And again, to remind you of what
11 we said yesterday we're not talking about is
12 the measure focus exactly the same. We're
13 asking are they conceptually the same because
14 there's going to be little, tiny differences
15 amongst these measures. And again as we said
16 yesterday we have identified those for you
17 that we would ask you to look at today.

18 CO-CHAIR TIRSCHWELL: Can I ask a
19 question about that? So, there's the
20 different target patient population but what
21 about the different target evaluation level,
22 like the clinician ones versus the facility

1 ones?

2 MS. JOHNSON: Those we actually
3 consider. Conceptually those would be, all
4 other things being the same, we would consider
5 those to be competing measures.

6 However, there often may be
7 reasons why you think that having the two
8 different levels of analysis is important. So
9 in that case you would say I cannot pick a
10 superior measure and here's one of the
11 reasons. We think it's important to have a
12 facility-level measure and a clinician-level
13 measure. Am I saying that correctly, Helen?

14 DR. BURSTIN: Yes. The only thing
15 I'd add is that in that case the most
16 important issue is really harmonization. So
17 for example, if you were talking, I think one
18 of your measures you're going to talk about is
19 some of the DVT prophylaxis work, clinician-
20 level versus hospital-level.

21 Granted the data systems are so
22 completely different in this day and age it's

1 almost impossible to get a measure that will
2 reflect both if you think both are important,
3 and in that case you would want to make sure
4 that the clinician-level assessment matches
5 the hospital-level assessment and is
6 harmonized on the most important data
7 elements.

8 CO-CHAIR TIRSCHWELL: And it would
9 seem to me that one of the reasons --
10 predicting why you might need a clinician-
11 level one and a facility-level one is that
12 there are these giant processes that are
13 rolling out that are going to be evaluating
14 clinicians on these levels and are already
15 evaluating facilities on these levels. And it
16 sort of seems you're, I don't know, you
17 probably need to endorse them both. Gail?

18 MEMBER COONEY: But wouldn't it be
19 cool if we had a way to like know when we were
20 looking at the same patient from the facility
21 assessment and the clinician assessment and
22 see whether we got the same conclusions?

1 DR. BURSTIN: So that really
2 speaks to I think what is the ideal state,
3 right? Wouldn't you love to have the measure
4 that rolls up and rolls down in terms of
5 higher levels of aggregation and down to the
6 clinician as appropriate. That's where I
7 think we all want to go.

8 I think just given where we are in
9 terms of data systems in America at this point
10 until we sort of get to some better data
11 infrastructure, particularly EHRs we hope,
12 that's harder to do.

13 MS. JOHNSON: Okay, and as we go
14 through this exercise in a few minutes once we
15 talk about -- just to kind of emphasize what
16 Helen said. Once we talk about competing
17 measures we will then ask you, if you say that
18 the differences are justified we will ask you
19 a little bit more about harmonization. So
20 that's kind of the second part of what we do.

21 So what we have here in the next
22 three slides are the thinking steps that we go

1 through to see whether or not things would be
2 recommended.

3 So, the first one here before we
4 even get to related and competing is does the
5 measure meet all four of the NQF evaluation
6 criteria. If you have said no then we do not
7 recommend it and we're done, and that's what
8 you guys have done this morning. If yes, then
9 are there potentially related or competing
10 endorsed or new measures? And if yes, then we
11 ask you to compare the specifications.

12 And at the conceptual level do the
13 measures address either the same measure focus
14 or the same target population. If so, if it's
15 the same measure focus but a different patient
16 population we ask is there a way to combine
17 the measures. And if so, then we would say
18 recommend the measure that has combined those
19 populations. Does that make sense? Hopefully
20 that makes sense.

21 If those measures can't be
22 combined in some way then we go down to the

1 next level and if the measures address the
2 same concepts for a measure focus for the same
3 population we call those competing measures.
4 And then what we do is we ask you to compare
5 the specs and basically we go through this
6 little exercise here.

7 If they're very similar we ask the
8 measure developers can they resolve the
9 stewardship so that they can create one
10 measure. That is a little more difficult if
11 the two different measures are from to
12 different developers obviously. Sometimes the
13 answer's yes and sometimes the answer is no.
14 If no, then you go on and compare both
15 measures on all of the evaluation criteria and
16 weigh the strengths and weaknesses across the
17 criteria and try to determine if you can
18 whether or not one measure is superior over
19 the other.

20 So for example, if one measure,
21 the validity you thought was iffy so the vote
22 was really close on validity on one, but you

1 were very happy with validity on another, then
2 that might be a reason that you would think
3 one is superior to another. That's just an
4 example.

5 Again, if you cannot recommend one
6 of those measures as superior then we would
7 ask you to say is there a justification for
8 having multiple measures. And if so, then
9 what you would be doing is putting forward
10 your recommendation that both measures would
11 be put forward. Otherwise you would -- and if
12 you do think one is superior then obviously
13 the one that you think is superior is the one
14 that would go forward. The one that you think
15 is not superior would go down at this point.
16 So it's very possible theoretically that
17 something that you thumbs-upped yesterday
18 could go down today because you think it's
19 just not quite as good as another one that's
20 very similar. Okay. And then if we can go to
21 the next slide.

22 Related measures we don't ask you

1 to choose the superior one because they are
2 going to be different either on the measure
3 focus or on the target population. But we ask
4 you to look at the specifications and see
5 whether or not they're completely harmonized.
6 And what's it say. Compare -- are they
7 completely harmonized? Yes. Recommend one
8 measure. I think technically that would be --
9 you would recommend both of those. Okay.

10 If they're not completely
11 harmonized then we ask you to consider are
12 there reasons that there are differences in
13 the specifications of the measures.

14 DR. PACE: I think what this is
15 going through -- sorry. I think we have a --
16 it's my slide. I'm sorry, I think there's a
17 confusion here. What's the next slide? Could
18 you go to that? Okay.

19 This is still -- and then go back.
20 So, I think what we're -- this is actually if
21 you're still talking about competing measures
22 and you've decided that you have to move

1 forward with both measures then you still want
2 some harmonization to the extent possible.
3 So, if you have two measures of -- well, we do
4 have two somewhat competing measures of
5 hospital-level mortality. There are some
6 differences but essentially they're trying to
7 get at measuring mortality. You may decide
8 that yes, we need both of those measures, the
9 30-day and the inpatient, and then we would
10 want them harmonized to the extent possible.
11 So, we can just go on then.

12 MS. JOHNSON: And I guess where --
13 I'm a little lost here, Karen. Help me out.

14 DR. PACE: So if you -- you would
15 want to send the -- we'll just move on past
16 this slide. The idea is that we would ask the
17 measure developers to look at opportunities
18 for harmonization. And you may have specific
19 recommendations. For example, the definition
20 of a readmission should be the same across
21 both measures.

22 MS. JOHNSON: So when you're

1 thinking about superiority, I think we've gone
2 through this but pretty much we want you to
3 think about impact, opportunity and evidence.
4 So that's criterion number one, importance to
5 measure and report. Think about the
6 scientific acceptability.

7 So here, this is a few more
8 examples. Untested measures cannot be
9 considered superior. In this phase we do not
10 have any untested measures, but in phase 2
11 it's actually likely that we may be seeing
12 some of those untested measures.

13 And then we would also have a
14 preference for measures with the broadest
15 application as well as those that address
16 disparities in care. So again, I think
17 yesterday I used the example of two measures,
18 one that looks at patients 18 and older versus
19 one that looks at 65 and older. We would
20 prefer one that has the more broad
21 applicability.

22 For usability we would prefer

1 measures and ask you to consider as superior
2 those measures that are actually being
3 publicly reported or in widest use or even in
4 use as opposed to perhaps just being planned
5 for use.

6 And then feasibility, obviously
7 measures that are based on electronic sources
8 versus ones that would require more manual
9 extraction, for example, might be considered
10 superior. Freely available. This speaks to
11 the mortality measure. We saw one this
12 morning that was based on the 3M algorithm for
13 the diagnosis classifications.

14 DR. PACE: However, that's
15 available.

16 MS. JOHNSON: It is available.
17 Yes, we found out this morning that we could
18 actually go in and look at that. But that
19 would be an example of what we used to think
20 wasn't freely available. Next slide, please.

21 Justification of multiple
22 measures. Basically what we're asking here is

1 to assess the value versus burden. So, what's
2 the value of having more than one measure
3 compared to the burden? The value is perhaps
4 there is an EHR-based measure that's very
5 similar to one that's paper-based and there's
6 good reason that you would want to bring
7 aboard an EHR-based measure as well. But
8 maybe there's measures with broader
9 applicability but still can't bring in every
10 patient population, every setting, that sort
11 of thing, as well as increased availability of
12 performance results. So, this may speak to
13 measures that have been around for awhile
14 longer.

15 Burden, again, are things like
16 increased data collection. Is it worth having
17 to collect data two or more times for two
18 different measures? And if you have multiple
19 measures do they give you similar results
20 across. Can you interpret them similarly?
21 And if not, then that's kind of a burden of
22 having multiple measures. So again you would

1 decide what you think about whether the value
2 of having multiple measures outweighs the
3 burden. And again, that's your expertise and
4 judgment that we're asking you to use here.

5 For lack of harmonization, again
6 that refers to having two measures that are
7 related but perhaps the specifications are
8 different. And again there may be
9 justifications for having different
10 specifications. So, what you want to do is
11 think about the evidence. Is there evidence
12 for one specification versus another.
13 Remember that different data sources may
14 require some differences in technical
15 specifications. So if you were having a
16 measure that's based on claims versus one
17 that's based on a paper abstraction they might
18 have to give different details of how to
19 abstract that data. They should not be simply
20 due to proprietary interests or preferences.

21 The difference -- we've already
22 addressed this. The difference would not

1 affect interpretability or burden of data
2 collection. And again, if it does affect
3 burden then you would decide as you would with
4 the competing measures for superiority does
5 value outweigh the burden. Okay, so next
6 slide.

7 Before we go onto the meat of the
8 discussion let me open it up for questions and
9 see what you think. Terry's laughing so
10 something's wrong.

11 MEMBER RICHMOND: I'm just
12 thinking I don't really have all that, but I
13 think going through it may be helpful. When
14 we do the measures I'll get it.

15 MS. JOHNSON: What we're going to
16 do today -- Risha?

17 MEMBER GIDWANI: I have just a
18 specific question. I'm trying to find the 3M
19 APR-DRG grouper online. So does anybody have
20 an actual link for that? The 3M website is
21 not proving fruitful for me.

22 CO-CHAIR TIRSCHWELL: The one

1 where they said all the details should be
2 revealed behind the magic curtain?

3 MEMBER GIDWANI: Do you need a
4 password for it?

5 CO-CHAIR TIRSCHWELL: My guess is
6 it's purposely hard to find, but --

7 MEMBER RICHMOND: Actually I think
8 they said that you need a password.

9 CO-CHAIR TIRSCHWELL: You probably
10 have to sign up, give your email address, your
11 firstborn.

12 DR. PACE: We'll get that in the
13 steering committee.

14 MR. GEPPERT: I'm sorry, this is
15 Jeff from AHRQ. I can give you the URL if you
16 want it.

17 MEMBER GIDWANI: Yes, please.

18 MR. GEPPERT: So it's
19 www.aprdrgassign -- A-S-S-I-G-N -- .com. And
20 you do need a username and a password but
21 hopefully there are instructions there.

22 MEMBER GIDWANI: If you don't

1 already have a login and there is no place to
2 register for one is there a basic login you
3 can give me?

4 MR. GEPPERT: We just have to use
5 the login information that they gave AHRQ. I
6 can try to email them quickly and see if they
7 can provide a guest password.

8 MEMBER GIDWANI: Okay. I just
9 can't register for one so that would be great.

10 CO-CHAIR TIRSCHWELL: So that's
11 probably not going to affect this so if you'll
12 move that offline for the moment.

13 CO-CHAIR KNOWLTON: Karen, I have
14 a question. Just -- it's not related to what
15 you said up there, but I noticed that in the
16 material you gave us that some of the things
17 that we are considering we did not consider as
18 a steering committee. How does that work?

19 MS. JOHNSON: Okay, how that works
20 is there may be measures, and there are
21 actually, that you guys did not consider in
22 this project but they have been considered in

1 other projects and are currently endorsed. So
2 we would still have you look at the
3 specifications. Obviously you will not have
4 gone through the entire thinking process that
5 you did with the measures that you looked at
6 in this project, but as best you can does one
7 look superior or is there room for
8 harmonization.

9 Basically if you decided, if you
10 had a competing measure from a different
11 project and you decided that the one that you
12 looked at in this project was not the superior
13 measure then what that would do is that would
14 take that one down. Okay?

15 If you decided that the other one
16 based on your brief review was not the
17 superior measure then really you don't have
18 any control over that. It would not affect
19 endorsement at all. It would just be your
20 information that you think that the one that
21 you looked at in this project is a better one
22 than the one that's out there already.

1 And let me ask Helen and Karen and
2 make sure I have that correct.

3 DR. PACE: Yes. Right now all you
4 can do is act on the measures that are in this
5 project. But we would like your
6 recommendation because that's something that
7 would then come up when that other measure is
8 up for endorsement again.

9 MS. JOHNSON: Any other questions
10 before we delve in? Okay.

11 If you have your homework from
12 last night that we passed out, and I don't
13 really expect you guys to have looked at these
14 in detail last night, but if you would pull
15 that up and go to the last set. I think it
16 should be group number five. We're going out
17 of order here because someone from the
18 developer team needs to leave a little earlier
19 so we're going to do the mortality measures
20 first. Okay.

21 CO-CHAIR TIRSCHWELL: Page 13 I
22 think in the handout.

1 MS. JOHNSON: Page 12 and 13? Oh.
2 It's mislabeled. It should be 5 I think.
3 Sorry about that. It's the last two pages.
4 Okay, so what I've tried to do
5 with this handout is to give you some really
6 basic information about the measures. So I've
7 given you the description, the numerator,
8 denominator, the exclusions, and then I've
9 actually gone through and told you what the
10 measure focus is and the patient population.
11 I've given you the time frame, setting and
12 level of analysis. And also data source.
13 And then we also put in --
14 actually, we don't have these. Are these the
15 new ones? Jessica is printing out the new
16 ones now. What we -- we have a new version of
17 this because when we handed this out last
18 night we had not done the stroke mortality
19 measures so we couldn't tell you what you guys
20 had voted. So we have more coming to you.
21 But I don't know necessarily that for
22 beginning our discussion if you have to have

1 that. Let's just walk through and see if we
2 can, see how far we get.

3 Let's think about the mortality
4 measures. We have one from AHRQ and one from
5 CMS. And since both are measuring mortality
6 and since both are measuring mortality in
7 stroke patients we consider them competing
8 measures. Okay? So since we're thinking of
9 them as competing measures we would like you
10 to think about whether or not you would
11 consider one of them superior. Salina.

12 MEMBER WADDY: 0467, isn't that
13 ischemic stroke and hemorrhages? Whereas the
14 others are just ischemic stroke?

15 MS. JOHNSON: You are correct. So
16 --

17 MEMBER WADDY: Do you all have
18 some other measure that's already ongoing for
19 hemorrhages? Other than this? Okay.

20 MS. JOHNSON: Operator, can you
21 mute those lines?

22 MEMBER J. BAUTISTA: I also think,

1 I mean inpatient mortality is very different
2 than 30-day mortality. So I have trouble
3 thinking of these as competing measures. I
4 think they're very different.

5 MS. JOHNSON: Again, we are
6 considering them competing because the measure
7 focus is mortality. So again it's a very
8 conceptual, very high-level way of thinking
9 about it. But it could very well be that in
10 your mind it's important to have an in-
11 hospital measure as well as 30-day longer
12 outlook. In which case you would -- that
13 would be one reason that you might say
14 multiple measures are justified.

15 DR. PACE: So let me -- can I just
16 add to that? So we start out with, you know,
17 the broad concepts, what it's trying to
18 measure, and then there may be very important
19 reasons that we should have an inpatient and
20 a 30-day and that's what we want you all to
21 weigh in on. So it's not that we're saying
22 that you will have to choose between them, but

1 we want to start with that discussion and then
2 go from there in terms of if there are
3 harmonization issues.

4 We prefer to do that then starting
5 with because there are differences that we
6 automatically accept that there should be
7 differences. So it's not that you're going to
8 have to but we want to at least introduce that
9 question for you to work through.

10 DR. BURSTIN: And just to give you
11 an example, for AMI which is actually very
12 similar we actually -- the cardiovascular
13 committee decided both inpatient and 30-day
14 were related but both important concepts.

15 MS. JOHNSON: I think David.

16 CO-CHAIR TIRSCHWELL: So I was
17 just going to comment that although they're
18 competing by that loosest of definitions I
19 think there are important differences which
20 probably do justify it. And just a couple of
21 the big ones are the inpatient versus 30-day.
22 That's a really big difference. And I prefer

1 the 30-day one in that scenario.

2 On the other hand, the inpatient
3 one has all ages and all stroke types whereas
4 the 30-day one is restricted in age to greater
5 than 65 and only ischemic stroke. So in that
6 one I actually prefer the inpatient one. So
7 I think there are sort of arguments on both
8 sides is my particular perspective.

9 MS. JOHNSON: Bill?

10 MEMBER BARSAN: Yes, so is there
11 ever the possibility on things like this -- I
12 mean, you know, what would be great is would
13 be to have one measure that looks at anybody
14 from 18 and over. You could split it out with
15 65 and over and then, you know, all the rest
16 of the adults. You could split out ischemic
17 stroke, you could split out hemorrhagic
18 stroke. But you just have one measure but you
19 just specify that it examine all those
20 different subtypes. That would be ideal
21 rather than having three different measures.

22 CO-CHAIR TIRSCHWELL: Can I just

1 respond back to that? I mean the
2 methodologies of these are so different that
3 that would be a totally new measure.

4 MS. JOHNSON: Karen?

5 DR. PACE: I mean obviously that's
6 also a preference for NQF. Measures that have
7 the broadest applicability capture the widest
8 target population indicated by the measure or
9 the evidence that you could do those kinds of
10 things, you know, inpatient and 30-day.

11 Unfortunately, you know, that's a
12 goal in the future and not our current
13 realities. But I think you could ask the
14 measure developer -- I don't know if these
15 particular measure developers have discussed
16 combining forces in any way to move toward
17 that goal.

18 MEMBER R. BAUTISTA: If I have two
19 measures, one is a hospital measure, the other
20 one being a clinician measure, and decide to
21 take the clinician but not the hospital
22 measure basically at the end, are we in fact

1 saying that we're no longer going to be
2 judging the hospital for example? For that
3 particular measure. Or is it going to apply
4 for both clinician and hospital at the end?

5 MS. JOHNSON: Just to clarify,
6 both of these are going to be hospital
7 measures that we're talking about right now in
8 group 5. But your question is more generally
9 if you had one versus the other. If you did
10 choose one to be superior then by definition
11 you would be saying that the other one you
12 would not continue to recommend for
13 endorsement. So the other one would go down.

14 MEMBER R. BAUTISTA: Right.
15 You're basically you're not going to endorse.
16 It's as good as non-endorsement then I
17 suppose, right?

18 MS. JOHNSON: Yes.

19 MEMBER R. BAUTISTA: Okay.

20 MEMBER COONEY: But couldn't we at
21 least like under the description one measures
22 both hemorrhagic and ischemic stroke, one

1 measures just ischemic stroke. Can we get
2 them to agree to both measure the same thing
3 there?

4 MS. JOHNSON: We could certainly
5 ask them to respond to that.

6 PARTICIPANT: Hi, this is -- from
7 Yale. I don't know, Susannah, are you still
8 in the room? Or she had to go catch a train.
9 If not I'll speak to that. Can you hear me?

10 DR. BURSTIN: She's here, are you
11 Elizabeth? And Susannah is still here as
12 well. So she's coming up.

13 PARTICIPANT: Okay, great. I
14 defer to her then.

15 DR. BURSTIN: Okay.

16 DR. BERNHEIM: So I think there
17 may be value to looking at hemorrhagic stroke
18 as well. The clinician group that supported
19 our measure development felt very strongly
20 that the combined was too heterogenous a group
21 to adequately produce a good 30-day risk
22 adjustment model. So I think we would need to

1 have conversations and the question really
2 might be about splitting out and developing a
3 second measure. But I think it would be hard
4 for our technical expert panel to swallow a
5 combined measure.

6 PARTICIPANT: I just want to point
7 out that the death rate for hemorrhagic stroke
8 is just so much higher as well.

9 MS. JOHNSON: David?

10 DR. ROMANO: This is Dr. Romano,
11 could I address that?

12 CO-CHAIR TIRSCHWELL: Sorry, go
13 ahead.

14 DR. ROMANO: So we both have had -
15 - internal discussion of this issue both with
16 the analytic group as well as expert panels.
17 And we generally take the perspective that
18 these cohorts for analysis of risk adjustment
19 mortality should be defined based on
20 characteristics of the patient that are
21 apparent before admission, presentation to the
22 hospital.

1 This is a very similar situation
2 that we have for example with heart attack
3 where we have FT elevation MI versus non-FT
4 elevation MI. Two pathophysiologically
5 different conditions with different outcomes
6 but patients don't know which one they have
7 and doctors don't know which one they have
8 before the patient arrives at the hospital.

9 Similarly, for heart failure we
10 have systolic and diastolic heart failure
11 combined. So in general for pneumonia we have
12 viral and bacterial pneumonia combined. So in
13 general we prefer to define the cohorts based
14 on clinical presentation that are clear in --
15 before patients arrive at the hospital or when
16 they first arrive in the emergency department
17 so that our analysis is not susceptible to
18 bias by the diagnostic process, or less
19 susceptible to bias by the diagnostic process.

20 But having said that we have as
21 Jeff Geppert alluded to earlier estimated
22 stratified models for ischemic and hemorrhagic

1 strokes, and we would certainly be willing to
2 consider. We have heard feedback from the
3 user community that they would like to see
4 separate mortality estimates for ischemic and
5 hemorrhagic mortality. So we would be willing
6 to consider stratified model with stratified
7 reporting with a composite measure then being
8 the primary overall outcome.

9 MS. JOHNSON: Michael.

10 MEMBER KAPLITT: So based on that
11 logic why not include patients who come in
12 with transient aphasia and then it turns out
13 they had a seizure from an undiagnosed brain
14 tumor that was only found out after they came
15 in? I mean, if you're going to base it purely
16 on their clinical presentation, you know,
17 based on that logic then you know, you would
18 include a lot of things that aren't even
19 strokes. So obviously there's something about
20 the diagnostic process that winds up
21 influencing this.

22 I think the discussion that we all

1 had this morning as people who treat these
2 things for a living is that we feel that
3 there's such a fundamental difference between
4 a hemorrhagic stroke and an ischemic stroke
5 that that does, you know, warrant potentially
6 special consideration. That's why we spent so
7 much time talking about it I think.

8 MS. JOHNSON: Dan? I'm sorry, go
9 ahead, Patrick.

10 DR. ROMANO: Oh, I was going to
11 say I think the point's well taken. It's a
12 gray line and certainly for other conditions
13 as well. The presentation of pneumonia is not
14 always clear, the presentation of heart
15 failure is not always clear. But -- and we're
16 trying to define -- we're trying to define the
17 right point on this spectrum to define a
18 clinical syndrome that has high mortality
19 where there's opportunities for intervention
20 to improve outcomes and where it's a
21 recognized entity by both patients and
22 clinicians. So, we acknowledge that you could

1 draw the line in different places and
2 certainly, as I said, we would be willing to
3 and have done some initial analyses to support
4 a stratified analysis.

5 MS. JOHNSON: Dan?

6 MEMBER LABOVITZ: I'm sorry to be
7 confused. I'd like to present myself as being
8 smart but I'm feeling dumb.

9 I don't see how we can harmonize
10 or relate these measures. They are about
11 death which gives me deep anxiety but I guess
12 I already said that. But beyond that they
13 have radically different engines underneath.

14 They just don't measure the same
15 thing, they really don't. The adjustments are
16 completely different, the data are different.
17 I don't see how you could -- if you could make
18 them look the same on this piece of paper but
19 they are always, always going to be radically
20 different. So what's the point?

21 DR. PACE: It's an appropriate
22 question and I guess the issue is, you know,

1 whether you all see any opportunities for
2 harmonization or not, or recommendations for
3 the future. Are there any ways to look at
4 these outgoing because they will come back for
5 endorsement maintenance. Perhaps not. But
6 you're absolutely right, you know, the
7 harmonization especially when you get into
8 these complex measures is much more
9 complicated than when you're talking about a
10 process measure.

11 MS. JOHNSON: Ramon, I think you
12 were next.

13 MEMBER R. BAUTISTA: I still don't
14 see why we can compare a hospital-based and a
15 practitioner-based measure. And then try to
16 pick one, it seems to be a little bit worse
17 compared to the other one. In other words,
18 we're actually going to be not endorsing
19 something that we endorsed before because it's
20 a little bit worse compared to another measure
21 that's meant for a totally different target
22 population. I don't understand that. It's

1 probably a backhanded way of trying to get rid
2 of something you didn't like in the first
3 place.

4 MS. JOHNSON: We will table that
5 question until we get to a set of measures
6 where one is facility and one is clinician.
7 Right now both of these are facility-level
8 measures. So we'll come back to your
9 question.

10 DR. PACE: I might just make one
11 comment though. At that level it's probably
12 going to be about harmonization, not choosing
13 one over the other.

14 MS. JOHNSON: Terry?

15 MEMBER RICHMOND: At this point I
16 would advocate keeping both. And I mean,
17 other than one is ischemic and hemorrhagic and
18 the other is ischemic only the methods are so
19 different that my understanding with the CMS
20 measure, the 30-day measure is we're using
21 historical data that are available in patients
22 over 65 years of age which is not available in

1 this broader population of 18 years and older.
2 And certainly with hemorrhagic and ischemic we
3 will see patients between 18 and 65 that we
4 would lose if we tried to bring those
5 together.

6 MS. JOHNSON: Did you have any
7 additional? Okay. Then David has to talk.

8 CO-CHAIR TIRSCHWELL: So I
9 completely agree and I guess the -- I would
10 move to suggest because I don't know that we
11 have the power to do anything else that a
12 little bit of harmonization would be to ask
13 the AHRQ folks if they would really move
14 forward with the subtype-specific models which
15 would allow a little bit of comparison granted
16 it's not the same thing. And I would also
17 implore them to divide stroke into three
18 categories, ischemic stroke, intracerebral
19 hemorrhage and subarachnoid hemorrhage which
20 are all quite different. And it's the classic
21 division of stroke subtypes. And thank God,
22 division by ICD-9 codes as well, so.

1 MS. JOHNSON: Any other ideas for
2 potential harmonization? Risha. I'm sorry,
3 Risha?

4 MEMBER GIDWANI: I just want to
5 say I agree with Daniel. I think that
6 harmonization is actually not going to work
7 very well in this case because the data
8 elements are extremely different. And I don't
9 see how they could be reconciled.

10 I would also love to be able to
11 compare the two models side by side in terms
12 of their coefficients, the variables they're
13 using for risk adjustment and to look at the
14 direction of the effect. Because when I look
15 at the AHRQ models, when I look at the
16 predictor variables, the direction of the
17 effect in terms of whether something is
18 protective or not against mortality has good
19 face validity. When I look at the CMS models
20 and I see things -- gosh, I have too many
21 papers in front of me. But you know, I see
22 that there's not very good face validity and

1 there are clinical conditions that are
2 protective against mortality -- here we go --
3 such as heart disease and aneurysm and
4 hypertension, you know, that leads me to not
5 only believe that harmonization is not going
6 to be possible but it puts my balance of favor
7 towards the AHRQ models if we do need to
8 choose one over the other.

9 MS. JOHNSON: Salina, did you --
10 was your question resolved?

11 MEMBER WADDY: Pretty much. I
12 just -- the last -- I completely agree with
13 the proposal that or recommendation or
14 whatever is currently on the floor. My only
15 question is about the age groups at this
16 point. Are we -- what are the age groups that
17 are under consideration for these? Is it over
18 18 and then the split with the greater than
19 65, or is it 18 and up for everything?

20 MS. JOHNSON: Well, as they stand
21 right now the AHRQ measure is 18-plus and the
22 CMS measure is only 65-plus. So I guess --

1 DR. BURSTIN: And just to speak to
2 that. This has been an issue. Obviously
3 these measures were developed for Medicare to
4 have the data that allows the cross-links
5 between hospitals.

6 In the past CMS and Yale have done
7 additional analyses to demonstrate whether the
8 risk model itself works for patients under 65
9 so it could be, for example, used for other
10 patients and settings. So that might be a
11 recommendation if you'd like the committee to
12 take a look at it.

13 MEMBER WADDY: Yes, I mean I think
14 it at least should -- I think it would be very
15 helpful to have over 18, but then I'm also
16 very concerned, and this may be beyond what we
17 do here, that you know, we could be excluding
18 a really important population which is care in
19 pediatric patients. And so I don't know if
20 you all have a pediatric care section that's
21 separate and if I'm just opening a giant can
22 of worms that maybe can be tabled for a later

1 time. But at least that --

2 DR. BURSTIN: Small can of worms.

3 No, it's actually a good question. We have
4 tried to eliminate any setting-specific or
5 population-specific committees because we get
6 into these issues of people being left out.

7 We have intentionally put a pediatric
8 neurologist on this committee to really kind
9 of keep us honest and say if there's measures
10 that come forward and go there's really no
11 reason this measure is X age and up, for
12 example. Isn't it --

13 MS. JOHNSON: I think it's Dr.
14 Sheth.

15 DR. BURSTIN: Who just left, yes.
16 So I mean I think it's fair game to indicate
17 if there's any of these measures that we're
18 looking at that are applicable more broadly
19 it's a good question for the developers.

20 MEMBER COONEY: I just was looking
21 at the exclusions and I don't see why they
22 can't be a little more consistent as well. I

1 mean, I know we can't completely harmonize
2 them and that they're different, but as much
3 as we can bring into synch as we can it just
4 seems we should.

5 DR. PACE: So, I think one of the
6 things that in terms of what we've heard so
7 far is that you all are thinking that the
8 value of having these two measures because
9 neither one can accommodate either all of the
10 patients and age or all of the strokes or a
11 variety of, you know, inpatient and 30-days.
12 That at this point in time you're saying that
13 the value of having those two measures is
14 there, and that perhaps you want the
15 developers to look at whether they can do any
16 harmonization with -- AHRQ is going to look at
17 whether they can do a stratification. And the
18 question that just came up is whether there's
19 any room for some alignment with the
20 exclusions that we could just ask the
21 developers to give you a response on that.

22 Is there anything else that anyone

1 wants to?

2 MEMBER WADDY: Just one more
3 thing. I think these were the two measures
4 that had the differences in transfers, how
5 they handle the transfers. So they may need
6 to really look at that.

7 DR. ROMANO: This is Dr. Romano,
8 can I address that?

9 MS. JOHNSON: Go ahead.

10 DR. ROMANO: Yes, I mean I would
11 say that for each of these two measures the
12 exclusions are the correct exclusions for the
13 type of data that are being used. So the CMS
14 measure excludes transfers that come in from
15 another acute care hospital because a death
16 that occurs after transfer is attributed back
17 to the hospital where the patient was
18 originally admitted and that's absolutely the
19 correct thing to do in a 30-day measure.

20 In an inpatient mortality measure
21 it's obviously not possible to make that
22 attribution. So, we're forced to exclude --

1 to avoid double-counting we're forced to
2 exclude the patients who are transferred out,
3 because when the patients transferred out then
4 we lose the information about their ultimate
5 outcome when they're discharged from the acute
6 care hospital. So I think that difference is
7 inextricably linked with the difference in
8 source data.

9 Otherwise our exclusions for
10 children and pregnancy are of course because
11 those are very peculiar populations with
12 respect to stroke. And for pregnancy there
13 are specific coding issues that make it much
14 more complicated to identify strokes and risk
15 factors for strokes. For children of course
16 strokes occur in the setting of very specific
17 high-risk chronic diseases that really make it
18 an entirely different clinical issue.

19 MEMBER WADDY: I do agree in our
20 previous discussion for I believe it was 2026
21 regarding how you handled transfers, but I
22 don't think that there is necessarily, at

1 least not agreement from me regarding how
2 transfers were handled in 0467, and whether or
3 not that's just a limitation of the data set
4 or there needs to be reconsideration of how
5 that data is collected. But it's an important
6 piece of information that I don't think should
7 be glossed over.

8 CO-CHAIR TIRSCHWELL: I do have
9 something related and that's that in the AHRQ
10 which are the administrative data which are
11 based on that UB-40 form with the diagnosis
12 codes I believe there's a field for admission
13 source which includes the possibility of
14 transferred in from another hospital. Am I
15 wrong about that, Patrick?

16 DR. ROMANO: Yes, point of origin.
17 And like I say, we do test that in all our
18 risk adjustment models. And it was not
19 significant for stroke mortality.

20 CO-CHAIR TIRSCHWELL: So it's not
21 that you couldn't exclude them, it's that you
22 decided not to.

1 DR. ROMANO: Correct. Our usual
2 approach is to adjust for it. So if it
3 reflects a more severe cohort of patients then
4 we want to take that into consideration in the
5 risk adjustment. In this case what we
6 effectively see, and we see this in some other
7 cohorts as well, is that some patients are
8 transferred after they survive the highest
9 risk period, and they're transferred for the
10 purpose of getting additional diagnostic
11 testing, maybe rehabilitation. Other patients
12 are transferred because they're getting worse
13 and they're beyond the capacity of the
14 original hospital to manage. So, there's a
15 washout essentially and that's why those
16 transfers don't show up as having higher
17 mortality.

18 MS. JOHNSON: Gwen?

19 MEMBER BUHR: So I was just
20 wondering if it would be possible for the AHRQ
21 measure to also stratify by 65 and older and
22 the younger ages so that they could be

1 somewhat comparable as well.

2 DR. ROMANO: Well, in general of
3 course there's a danger to multi-way
4 stratification because that leads to smaller
5 cell sizes and less reliable estimates. But
6 you know, we're certainly willing to hear
7 different opinions. In general our expert
8 committees and our stakeholders have favored
9 including all adults.

10 MS. JOHNSON: Risha?

11 MEMBER GIDWANI: I think given the
12 vast number of strokes that occur in the
13 United States every year the cell sizes would
14 be sufficient even if you do stratify 65 and
15 above and lower than 65.

16 I think given the comments by the
17 American Academy of Neurology indicating that
18 different risk adjustment models will rank
19 hospitals relatively differently using, you
20 know, depending on their own risk adjustment
21 methodology this would be a really great way
22 for when these measures come up for

1 maintenance to get some data about how AHRQ is
2 evaluating hospitals with patients above 65
3 versus how CMS is.

4 And even noting the difference in
5 30-day versus in-hospital mortality one would
6 assume that the direction of effect of those
7 measures would be in the same direction. And
8 so I think just in terms of the fact that the
9 field of risk adjustment is relatively new
10 this would provide some valuable feedback as
11 to the ability of risk adjustment to rank
12 hospitals in a consistent manner.

13 DR. BOTT: This is John Bott with
14 AHRQ. This is a question more so for Jeff,
15 but I believe stratifying by age is one of
16 the, what we call canned stratifiers within
17 virtually all or all our QIs. Is that
18 correct, Jeff? So the person currently has
19 the ability to stratify by age, not just 65
20 and up but by various ways.

21 MR. GEPPERT: Yes, that's correct.
22 That's a feature of the software that

1 implements the AHRQ measures, stratification
2 by age.

3 MS. JOHNSON: Does anyone else
4 have any other ideas for harmonization or have
5 we pretty much covered them? Risha?

6 MEMBER GIDWANI: I just have a
7 follow-up question to that response. Does
8 that mean that the expected mortality is also
9 stratified by age, or is that just the
10 observed mortality that you can stratify by
11 age?

12 MR. GEPPERT: It's both. So the
13 difference I think between just simply
14 reporting the rates stratified by age and
15 developing a separate measure that's
16 stratified by age is you would develop a
17 separate risk model for the strata. So the
18 data is slightly different.

19 MEMBER GIDWANI: You're saying --
20 wouldn't the risk model be the same? It would
21 just include a data set that had patients 65
22 and older.

1 MR. GEPPERT: I'm saying that if -
2 - there's two options. You can either just
3 stratify the rates by age. In that case it's
4 the same risk model and you simply stratify
5 the rates, divide the patient population into
6 two. But the suggestion of creating a
7 separate measure that is stratified by age you
8 would actually develop a separate risk model
9 for that strata. You have a separate set of
10 coefficients and you would estimate it
11 separately.

12 MEMBER GIDWANI: Okay, thank you.

13 MS. JOHNSON: And Karen and Helen,
14 I'm unclear. Is there any voting in this
15 section?

16 DR. PACE: Not necessarily. So I
17 mean, unless anyone disagrees with what has
18 been brought up before in terms of is it -- if
19 anyone wants to call the question certainly we
20 can. But the -- what we're hearing is that
21 people see value in having both of these
22 measures. So is there anyone who wanted to

1 speak to the contrary? Okay. All right.

2 MS. JOHNSON: Okay, great. We've
3 gotten through one of our many that we wanted
4 to discuss. The second one is probably very
5 easy. I put it up here more for completion
6 than anything, but that is actually thinking
7 about the two CMS measures, one for mortality,
8 one for readmission. Those are related
9 measures and it might be at this point easier
10 just to ask the developers are these measures
11 harmonized in order to your definitions and
12 such. Obviously your risk model is different
13 but the approach is the same.

14 PARTICIPANT: So the measures are
15 actually harmonized. There are some
16 differences as we discussed earlier,
17 particularly around transfer patients. So the
18 readmissions. In a case where the patient is
19 transferred the mortality would be attributed
20 to the hospital that first admitted the
21 patient and the readmission is attributed to
22 the hospital discharging the patient to the

1 non-acute setting. So in those cases that
2 would be different.

3 For the mortality measure we
4 randomly select one hospitalization a year if
5 a patient has multiple hospitalizations and
6 for the readmission measure we don't do that
7 but we do block out any admissions that occur
8 within 30 days of an index admission so that
9 no hospitalization would be considered both an
10 index admission and a readmission.

11 Obviously the risk adjustment
12 variables that feed into the model are
13 slightly different because they're different
14 outcomes. But in other ways they are aligned
15 sometimes.

16 DR. PACE: So I don't think
17 there's really any issues that -- unless
18 anyone in the committee has identified
19 anything.

20 MS. JOHNSON: Okay, let's go back
21 to measure group number 1. So flip back to
22 the beginning of your handout.

1 Okay, just to orient everybody
2 this is the set of measures that looked at
3 antithrombotic therapy. Two measures looked
4 at discharge. So was antithrombotic therapy
5 ordered at discharge or prescribed at
6 discharge. And then another one, was it done
7 by end of hospital day two.

8 So if you compare the two -- if
9 you compare the two Joint Commission measures,
10 one looking at therapy by discharge, the other
11 looking at therapy by hospital day two, we
12 could consider these either related or
13 competing. And I guess our question was was
14 there any feeling from the committee that
15 these might be combined in some way or is it
16 necessary to have two measures. If we can
17 just get some discussion on that.

18 CO-CHAIR TIRSCHWELL: I guess I
19 would throw out to the developer who I guess
20 is the Joint Commission as to -- because both
21 of these measures were also kind of topped out
22 or pretty close to topped out. At the patient

1 level, and maybe they don't have this
2 information.

3 It might be something they could
4 query the Get With the Guidelines people, but
5 at the patient level if you always achieve the
6 day two and then you always achieve the
7 discharge one maybe you don't need the
8 discharge one if you've gotten the day two.
9 So you know, where is there more room for
10 improvement? If they're, you know, almost 100
11 percent linked we might be able to collapse
12 into one, but I think somebody would have to
13 sort of analyze some data. And again, it's
14 probably best done from Get With the
15 Guidelines. They might want to work with them
16 to see if they could figure out that type of
17 thing.

18 MS. WATT: This is Ann with the
19 Joint Commission. Karen and I are both here
20 and we're both going to answer. The answer to
21 your question, yes, we do have the capacity to
22 look at relative results for the same patient

1 for both measures and that's a good
2 suggestion. It's something we can do. But
3 we're not entirely certain that these are --
4 that they have the same focus. And I'll let
5 Karen address that.

6 MS. KOLBUSZ: I think that how we
7 see the focus is in the management of the
8 patient. And stroke 5, which is
9 antithrombotic by end of day two, is really
10 looking at early management of the patient,
11 giving that aspirin as soon as possible after
12 arrival. Whereas stroke 2 which is discharge
13 on antithrombotic is looking at secondary
14 prevention, long-term antithrombotic therapy.
15 So the focus is very different in our opinion.

16 CO-CHAIR TIRSCHWELL: Just to
17 reply to that, I would think -- it's a good
18 point. I think that you would -- probably
19 wouldn't get rid of the day two one, but it's
20 possible in my mind that you might be able to
21 get rid of the discharge one if they're just
22 continuing along.

1 MEMBER WADDY: I also think --
2 weren't there differences as well between
3 these two in terms of the inclusion of TIAs?

4 MS. JOHNSON: We're looking at
5 0435, 0438.

6 MEMBER WADDY: Right, no --

7 MS. JOHNSON: So look at the
8 second and third columns of that sheet first.
9 We're doing those two first.

10 MEMBER WADDY: Oh, okay. Okay,
11 got it.

12 MS. JOHNSON: Jocelyn.

13 MEMBER J. BAUTISTA: So I really
14 like the idea of combining the two measures
15 similar to what they've done with some of the
16 core measures, the appropriateness of care,
17 composite measure. What percentage of
18 patients receive appropriate care at both time
19 points. If we've topped out at each one then
20 we should move to the next level of, you know,
21 what we expect of patients, of providers, that
22 you have appropriateness of care across all --

1 across the entire hospitalization.

2 MS. JOHNSON: Any comments on that
3 from the developer?

4 MS. WATT: Wouldn't it be easier
5 if we moved back over there? Okay, I'll do
6 that. Are you asking us -- I'm sorry, what
7 was the question?

8 MS. JOHNSON: One of the members
9 has suggested that you actually build a
10 composite measure that would include both of
11 these things. Or an actual all-or-none, yes.
12 I'm sorry.

13 MS. WATT: Well, sure, we could
14 make one measure out of the two of these. It
15 doesn't change anything in terms of the burden
16 of data abstraction or anything else. They
17 are already completely harmonized in terms of
18 data elements and data element definitions and
19 that kind of a thing.

20 DR. PACE: I think the suggestion
21 though is not so much to decrease the burden
22 about data collection or harmonization, but

1 it's telling you more than each one singly.
2 It's telling you whether each patient got both
3 things that are appropriate. Is that what
4 you're getting at?

5 MEMBER KAPLITT: The question is,
6 and this is the question that you asked is do
7 we have data on -- what percent that get the
8 two-day aspirin don't wind up getting
9 discharged on -- or whatever it is for reasons
10 other than medically appropriate reasons,
11 right? Someone gets an antithrombotic and
12 then they bleed and then they get discharged
13 without it. That's appropriate, but that's
14 going to wind up being excluded anyway or
15 adjusted or whatever.

16 So what percentage of patients do
17 people start them on antithrombotic and then
18 forget to discharge them on it, or choose not
19 to for inappropriate reasons or something?
20 Because if the data indicated that that was a
21 vanishingly small number then there would be,
22 you know, then it is an unnecessary burden,

1 the second one.

2 MEMBER KAPINOS: May I ask -- are
3 we expecting an answer?

4 MS. JOHNSON: Yes, go ahead.

5 MEMBER KAPINOS: To me I thought
6 we said that the second one -- so upon
7 discharge the antithrombotic, somebody
8 convinced me when we voted that it was a
9 little bit tied to the correct antithrombotic
10 for the etiological work-up. So upon
11 discharge if you are on aspirin when actually
12 on day three you were found to have a-fib then
13 that's wrong, right? So the -- so if we
14 combine the two then we will lose the fact
15 that the second measure, measuring a discharge
16 was also trying to make sure that the accurate
17 antithrombotic is matching the etiological
18 diagnosis.

19 MEMBER KAPLITT: So where does it
20 do that?

21 CO-CHAIR TIRSCHWELL: I guess I'm
22 not sure that it does that. I mean, there is

1 the second measure about a-fib, but other than
2 that there's nothing specific about the
3 antithrombotic agents. Do you guys want to
4 respond to that?

5 MS. KOLBUSZ: All I was going to
6 say in that regard is that we do use that
7 table of medications as the doctor pointed
8 out. And for stroke 2 generally it's aspirin
9 that they're receiving on arrival. But there
10 are other medications considered usually at
11 discharge. So you might lose that
12 granularity.

13 MS. JOHNSON: Jack?

14 MEMBER SCARIANO: Yes, I think
15 that actually we should have the two of them.
16 You know, I just don't think that actually
17 stroke patients get discharged and they aren't
18 on aspirin. I mean, the overall data that we
19 talked about yesterday, it's just bad data.
20 I just know people in private practice and it
21 isn't showing up in the chart audits because,
22 one, we either just tell them that at home you

1 should take aspirin or two, is that they're
2 already on aspirin. But as he's saying that
3 actually doctors have discharged patients who
4 have had strokes and they aren't taking
5 aspirin I think is not right. I just don't
6 think that that data is actually valid.

7 MEMBER WADDY: Actually, if I
8 remember correctly, and I'll have to pull up
9 the information but I think that they did find
10 that in regards -- that African-Americans were
11 less likely to be taking aspirin after
12 discharge. And that's actually why we have a
13 couple of initiatives or research projects
14 right now in order to improve that transfer
15 from the hospital to the outpatient setting in
16 order to improve compliance with that.

17 Whether or not -- how much of that
18 is due to prescribing habits versus either
19 filling prescriptions or paying for it is not
20 entirely clear, but I don't think the evidence
21 is there to refute that at this point.

22 MS. JOHNSON: Ramon?

1 MEMBER R. BAUTISTA: The idea of
2 harmonizing stroke 2 and stroke 5 will have to
3 take into account along with the plans for
4 0325 as well. We just can't harmonize without
5 taking 0325.

6 MS. JOHNSON: Michael?

7 MEMBER KAPLITT: I guess just a --
8 you know, in isolation yesterday part of what
9 we did with 1b was we looked at, you know,
10 what the performance gap was. And rereading
11 this, so the performance gap for 0435 you said
12 was something like 2 percent, and part of our
13 discussion was those are small percentages but
14 big numbers of people. So it was about 2
15 percent for 0435 and it was 3 to 4 percent for
16 0438.

17 So the question is is it largely
18 the same 2 to 3 percent. That's the
19 fundamental issue because in isolation we
20 looked at it that way and we felt that there
21 was a need. But now the whole purpose of this
22 process is to say are those the same people.

1 Do we really need to spend our time? So the
2 question is is there data on it, could we
3 generate. I mean, that's I guess what we'd
4 have to ask the developer.

5 MS. JOHNSON: Would the Joint
6 Commission care to speak to that point?

7 MS. WATT: Are we still discussing
8 0435 and 0438? Because we just sort of threw
9 in 0325 too. But if we're talking about 0435
10 and 0438 yes, we can look at the data to see
11 if patients meeting one meet the other.

12 MS. JOHNSON: Okay, thank you. So
13 I think what I'm hearing is that the committee
14 has said that creating a composite measure
15 might be something that you'd be interested in
16 seeing. And it sounds like the Joint
17 Commission could actually give some
18 information about that.

19 CO-CHAIR TIRSCHWELL: Just one
20 final comment. I realize that the data burden
21 isn't any different if you combine the two and
22 you either meet both or you don't. But it is

1 true that that is a higher standard. And so
2 almost by definition even if there's only 90
3 percent overlap there's going to be more
4 fallouts on the new measure than with either
5 one combined.

6 And we're not supposed to probably
7 dictate too much, but I mean, it's a way to
8 sort of take the ceiling down a little bit and
9 leave more room for improvement in an area
10 that we all thought was extremely important
11 but was getting towards the top. So now you
12 could move it down and leave a little bit more
13 room for improvement.

14 MS. WATT: I think it's a point
15 well made.

16 MS. JOHNSON: Thank you. I think
17 we're going to go ahead and go to the next set
18 of measures.

19 MEMBER SCARIANO: I've still got
20 one more comment. Yes, I still think that we
21 should have both of them. Again, even the NIH
22 data, it's probably due to actually lack of

1 access. But actually my point is that doctors
2 in private practice or neurologists in private
3 practice, and even internal medicine doctors,
4 we do not send your stroke patients home and
5 actually not give them aspirin. It's shown in
6 the charts that actually maybe it's not in the
7 charts. It is higher at actually two days is
8 because everyone writes it in the charts at
9 actually two days.

10 But if they already have aspirin
11 at home or we just tell them, I know I just
12 tell my patients just take, you know, 80 mg of
13 aspirin. And I usually don't write it down.
14 The actual discharge data is not accurate. I
15 just think that patients who have stroke, they
16 always go home, I'd say 99 percent of them go
17 home on aspirin.

18 MS. JOHNSON: Okay, anymore
19 comments before we close this one and go to
20 the next one? Okay, let's talk about the
21 measure 0325 versus 0435. So to remind you
22 one is an AMA-PCPI measure measured at the

1 clinician level, the other is the Joint
2 Commission measure, the discharge on
3 antithrombotic therapy that we were just
4 discussing.

5 So the differences besides the
6 level of analysis obviously is -- probably one
7 of the big differences is the TIA group in the
8 population of the AMA-PCPI measure. And also,
9 obviously I'm not a clinician. I couldn't
10 tell if it was the same list of drugs or not.

11 So, I guess the first question to
12 ask is can one be considered superior or do
13 you feel the need to have two different
14 measures. Bill?

15 MEMBER BARSAN: Well you know,
16 another difference was that the one also
17 includes TIA patients and the other one
18 doesn't.

19 MS. JOHNSON: Right.

20 MEMBER BARSAN: So that's kind of
21 a big difference.

22 MS. JOHNSON: I'm sorry, I thought

1 I said that. But you're right, that is a huge
2 difference. Right. Ramon?

3 MEMBER R. BAUTISTA: Again, the
4 fact that you have two different levels here
5 is like comparing apples and oranges now. I
6 mean, I don't think you can really compare and
7 say, you know, one is better. They are two
8 different measures as far as I can make out.

9 DR. PACE: I think the question is
10 -- I think the first question is is this --
11 which you've already answered by saying the
12 measure was suitable for endorsement is that
13 it's appropriate to measure at both the
14 clinician level and the facility level. So I
15 think by moving those measures forward that
16 decision has already been made.

17 So there are differences and the
18 question is -- and I think we'll just grant it
19 here because they come from different data
20 sources that in reality they can't be combined
21 into one measure in the current environment
22 that we have.

1 So the question is are these
2 differences indicated? Should one include TIA
3 and the other one not? Should they both
4 include TIA? And are the med lists
5 appropriate? So I think for these we're
6 looking at the harmonization and what does the
7 evidence say really should be the measure
8 focus and denominator population.

9 MS. JOHNSON: David?

10 CO-CHAIR TIRSCHWELL: So I would
11 suggest that the 0325, the PCPI measure, give
12 strong consideration to removing the TIA. I
13 think although I'm not suggesting TIA is not
14 an important condition I think there is so
15 much as we call it "squishiness" in the
16 diagnosis of TIA that you really could be led
17 astray by that. And with ischemic stroke it's
18 much clearer and I think is probably a better
19 consistent performance measure.

20 MS. JOHNSON: Fred?

21 MEMBER TOLIN: Actually, David, I
22 agree with that 100 percent and for that

1 reason I would really view looking at stroke
2 and the Joint Commission measure as really in
3 some ways superior to the muddiness that we
4 see with the TIA sort of garbage list if you
5 will.

6 MS. JOHNSON: Michael.

7 MEMBER KAPLITT: Here's the
8 process concern I have. So I agree with you
9 in principle. The process concern I have is
10 that if we're agreeing that these are two
11 separate measures and that we're not going to
12 be using this issue to decide on superiority
13 of one over the other because we've already
14 decided we're going to keep both then the
15 question I have is it seems to me we're
16 essentially revisiting something we did
17 yesterday.

18 If TIA is that much of a problem
19 why did we approve it yesterday? Because
20 we're not now evaluating TIA saying that
21 that's the crux of how we're going to decide
22 between these two. We're saying that we don't

1 think it's a good measure and that's
2 different.

3 DR. BURSTIN: I think -- and it's
4 an excellent point. I think part of what's
5 different today than yesterday is yesterday
6 you're looking at a measure in isolation. So
7 today you're looking at it and you're saying
8 will you get valuable results if you have a
9 clinician measure and a hospital measure that
10 are in fact different because the populations
11 they serve are different. So the other
12 possibility would be to ask PCPI to have a
13 stratified rate, one for stroke, one for TIA.

14 MEMBER KAPLITT: I'm not
15 disagreeing with that, except the discussion
16 we were just having is how valuable TIA is and
17 that, you know, I mean that to me seems
18 fundamental to whether or not that was an
19 appropriate measure to endorse. I agree with
20 your point but that's not what we were talking
21 about just now.

22 CO-CHAIR TIRSCHWELL: My opinion

1 is that yesterday it wasn't important enough
2 to not endorse, and that today we're
3 potentially looking at just harmonization and
4 potentially a small improvement. I mean, I
5 think they easily could have taken away from
6 yesterday's conversation that maybe they want
7 to reconsider the TIA thing and the suggestion
8 that giving a stratified rate might be the
9 first step towards convincing them whether or
10 not TIA is a relevant thing to continue to
11 include.

12 MS. JOHNSON: Greg, is your hand
13 still up? No. I think Jocelyn.

14 MEMBER J. BAUTISTA: I think if we
15 remove TIA then they're essentially the same
16 metric. You know, so there are minor
17 exclusion, you know, length of stay exclusion,
18 things like that, but then we're essentially
19 the same metric. We're measuring the same
20 processes in the same patients, whether
21 they're discharged on antithrombotic therapy.
22 And the only real difference then is this one

1 variable of physician, right? So if you just
2 add that one variable physician into say the
3 Joint Commission metric you have all the data
4 you need to stratify it by physician. Why do
5 we need a whole `nother data set?

6 MS. JOHNSON: Would anybody like
7 to comment on that?

8 MEMBER BARRETT: I think it was
9 said before that it may be that many hospitals
10 may not report the Joint Commission metric if
11 they're not trying to achieve certification.

12 DR. PACE: So I think one of the -
13 - that's an excellent question of why you
14 can't have one measure that you can compute
15 performance at the facility and the clinician
16 level. So the question would be whether the,
17 for example, the facility data captures the
18 clinician so that they could actually do that,
19 or whether the clinician-level measure
20 actually captures hospital data.

21 MEMBER J. BAUTISTA: So we're not
22 advocating who collects the data, right?

1 We're just advocating the metric and the data
2 elements.

3 DR. PACE: Well, the problem is
4 that a lot of the detailed specifications are
5 very much tied to a data source. So, ideally
6 you would be able to, you know, if you don't
7 get to that level of detail then you're not
8 exactly sure how exact the measures are. You
9 get even more error in these measures than,
10 you know, just what you normally have.

11 So that's the reality that we're
12 in is that we have these different data
13 sources and measure developers that specialize
14 in a data source, and we -- maybe when we get
15 to electronic health record measures that will
16 be an easier lift in terms of having measures
17 that can accommodate both. But, I think it's
18 a question that comes up over and over and we
19 might want to have the developers respond to
20 whether their measure could accommodate the
21 other level.

22 MS. WATT: This is Ann and

1 presently I don't believe hospitals have the
2 capability of collecting data from physician
3 billing records which is the data source for
4 the 0325 measure. I agree --

5 DR. PACE: Right, and I don't
6 think that would be the issue. It would be
7 the measure as you specified but having a
8 physician indicator so that then you could
9 compute that measure for a physician level.

10 MS. WATT: Well, you know, I can't
11 speak to how the data are collected for the
12 PCPI measures. You know, I suppose that
13 that's a possibility. I can tell you that to
14 the extent possible we believe that the data
15 elements and so forth are harmonized between
16 these two measures.

17 MS. JOHNSON: Dan, you've been
18 waiting for quite awhile.

19 MEMBER LABOVITZ: I beat this
20 horse yesterday. I'm going to do it again but
21 I'll keep it brief.

22 I agree with David Tirschwell, TIA

1 is a quagmire, a cesspool. It's full of
2 silliness. But fundamentally transient
3 ischemic attack and ischemic stroke are the
4 same disease separated only by luck. In TIA
5 you have rapid re-vascularization or excellent
6 collaterals, but aside from that they're the
7 same disease, the same pathophysiology, the
8 same approach to secondary prevention.

9 Abandoning it because doctors are
10 undisciplined about applying the diagnosis is
11 sending the wrong message and it's not
12 logical. The demand on us is really better
13 diagnosis and I think if we -- I think we have
14 the capacity to look for that from this
15 perspective. I applaud the AMA for saying
16 yes, we've got to do it even though it's bad.

17 MS. JOHNSON: So I think what I'm
18 hearing right now in the table is in terms of
19 harmonization there's one idea of taking out
20 the TIA patients. The other idea is maybe
21 seeing if the AMA group could stratify so that
22 you could keep your garbage diagnosis but be

1 able to compare those measures. Is there --
2 did I miss something? Is something else on
3 the table?

4 MEMBER KAPLITT: I still think
5 that Jocelyn's point is well taken. Because
6 I think that we're starting to buy into the
7 idea that, you know, inherently there's, you
8 know, the physician measure and the hospital
9 measure are two separate things. I still
10 don't necessarily buy into that point in this
11 case.

12 So in a situation where your
13 measuring let's say use of antithrombotics in
14 hospital versus use in general practice then
15 there is a big distinction between a physician
16 measure because you're not going to capture
17 all of that with hospital data.

18 But in this case the definition of
19 both of these are at discharge. By definition
20 discharge is from a hospital. So I still do
21 not understand the distinction between in this
22 particular case with these hospital-based

1 measures -- I know they're different data sets
2 that we're collecting from it. I don't
3 understand the distinction in terms of what
4 we're measuring because the ultimate goal --
5 yes.

6 So in one case you're going to be
7 able to tell individual physicians how they're
8 doing. In the other case you're going to be
9 able to tell the hospitals. But if the goal
10 is to get the patient to -- is to get more
11 patients to get the right care at the end of
12 the hospitalization, then if the hospital data
13 is collected and that hospital is doing poorly
14 they can then get granular on why they're
15 doing poorly.

16 CO-CHAIR TIRSCHWELL: The only
17 other thing I was going to suggest was I guess
18 I don't know how what we do or what we say can
19 influence things, but you know the idea would
20 be that you wouldn't have two separate,
21 totally distinct pathways for reporting for
22 what is essentially the same data.

1 And so you know, how do we support
2 the coming together so that there's just one
3 data collection that can feed multiple
4 systems. And I mean, if the suggestion is
5 well, we have to toss one of the measures well
6 then maybe we should. But it seems to me that
7 the goal has to be that this vast array of
8 parallel redundant data systems need to be
9 combined.

10 MS. JOSEPH: This is Diedra at the
11 AMA-PCPI. Can I comment on any of the
12 discussion?

13 MS. JOHNSON: Yes.

14 MS. JOSEPH: So, thank you for the
15 opportunity. I'm sorry I didn't jump in
16 earlier. I didn't know if I needed to wait
17 until the end.

18 So with regards to inclusion of
19 TIA I just wanted to explain kind of the
20 clinical expert panel's thoughts behind
21 including it in the measure. We did discuss
22 harmonization with the Joint Commission

1 measure as we were developing the measure and
2 during the maintenance and review of the
3 measure.

4 The intention was to have a
5 broader applicability and I think as someone
6 stated earlier that the TIA patient --
7 evidence does support the use of
8 antithrombotics in TIA patients. And the --
9 even though coders might suggest a diagnosis
10 the physician ultimately has to sign off on it
11 and is responsible for the accuracy of the
12 coding and how the diagnosis is coded.

13 And so since evidence supports the
14 use of antithrombotics in TIA patients we
15 thought -- and because there is still an
16 existing gap in care then the clinical expert
17 panel decided to leave it in. And again,
18 because of the broader applicability issue.

19 With regards to an additional
20 question or statement that was made regarding
21 combining the measures or just having one
22 measure versus having a facility-level and a

1 clinician-level measure, our measure specified
2 at the clinician-level but our measure results
3 can be aggregated at a higher level of
4 measurement.

5 Still I would -- we would advocate
6 for both measures being endorsed only because
7 it is important to, number one, to capture the
8 information at -- so that clinicians can know
9 how they're doing with regards to
10 accountability and so that hospitals can know
11 how they're doing with regards to
12 accountability. And also because -- sorry
13 about that. I'm losing my place. Also
14 because the measures are included in different
15 national programs, and things like PQRS and
16 meaningful use. And so getting rid of, or
17 losing the endorsement for one of the measures
18 might cause the measures to no longer be
19 included in national programs. And it's
20 obviously important for the data to be
21 collected in order to improve quality. So
22 that's what I had to say about that.

1 I don't know if anyone had any
2 specific questions for me but now that you
3 know I'm on the phone feel free.

4 MS. JOHNSON: Jocelyn?

5 MEMBER J. BAUTISTA: So I
6 completely agree with what Dave said earlier.
7 I would vote for getting rid of one of the
8 measures and I would vote for keeping the
9 Joint Commission measure.

10 MS. JOHNSON: Mary?

11 MEMBER VAN DE KAMP: My concern
12 with getting rid of the -- of just keeping the
13 one Joint Commission is you haven't gotten to
14 the physician level. And so are you saying
15 add to?

16 MEMBER J. BAUTISTA: Right. So
17 you know, when my hospital sees that one
18 physician is not performing the way it's
19 expected they let that physician know. So
20 that data would not be lost.

21 MEMBER KAPLITT: And in reverse if
22 a hospital is at 100 percent compliance then

1 what more do you need to know.

2 MEMBER VAN DE KAMP: So you're
3 going to drill down from the facility.

4 MEMBER J. BAUTISTA: Hospitals
5 will, yes.

6 MEMBER KAPLITT: If a hospital is
7 being told that they're lousy and that's
8 affecting their thing, they're going to get
9 into it, believe me. Whereas vice versa,
10 individual physicians may say all right, I
11 have special reasons why I'm, you know,
12 different.

13 MS. JOHNSON: Helen?

14 MEMBER COONEY: And you could
15 actually look at the physician level in the
16 outpatient setting once they're really
17 established back in the community rather than
18 at discharge and perhaps get complementary
19 information.

20 MEMBER BARRETT: I just want to
21 remind everybody the same thing I said before,
22 that the performance gap is really different

1 on these two measures. So we really don't
2 know that all the providers were captured in
3 the facilities.

4 DR. BURSTIN: Just to add in, I
5 think this is a great discussion. It sounds
6 like it is a future tense as opposed to at the
7 moment. So the question I would also have is
8 can we ask the Joint Commission and PCPI to
9 think about if there are some opportunities to
10 potentially have clinician-level indicators
11 out of the Joint Commission measure which
12 seems ideal.

13 But also do keep in mind one of
14 the reasons for the PCPI measure which they
15 have harmonized to the extent of at least with
16 the exception of the TIA issue is that it
17 allows physicians to report through PQRS. So
18 it is at least harmonized and gives them,
19 particularly neurologists I think a measure to
20 put forward as part of that program.

21 If it is fully harmonized and it's
22 information that's complementary it seems more

1 to me at least like a longer term issue to
2 potentially ask the Joint Commission and PCPI
3 to bring those together so you could actually
4 extract from what one of them does information
5 on both.

6 Again, the optimal situation is to
7 be able to cascade up and down to understand
8 where there are issues and where there are
9 problems and point towards where improvement
10 needs to be.

11 MS. JOHNSON: Jolynn?

12 MEMBER SUKO: I guess one thing
13 that I would say is that the administrative
14 burden of collecting this on both sides and
15 the difference in validity as has been pointed
16 out I feel like I'm again beating a dead
17 horse, so probably annoying.

18 But one thing I would suggest to
19 the AMA-PCPI is that these are the same
20 patients that the Joint Commission is
21 abstracting on. And can you test your
22 measures at a patient level against the Joint

1 Commission's measures? Because my hunch is
2 that many of the same -- if you took one
3 practice, that practice at a hospital who was
4 participating in PQRS and you took the Joint
5 Commission measures you could measure -- that
6 would be an effective test of the validity and
7 the opportunities to reduce that
8 administrative burden.

9 MS. JOSEPH: I'm sorry, this is
10 Diedra at the AMA. Could you further clarify
11 what you're saying? I got a little confused
12 because you said hospitals participating in
13 the PQRS system but it's actually at the
14 individual physician level that data is
15 submitted to PQRS.

16 MEMBER SUKO: Thanks, I -- what
17 I'm saying is that you're measuring
18 conceptually the same thing. And likely those
19 patients that you're submitting to the PQRS,
20 while you're doing it on a different -- with
21 a different method and claims form, the
22 hospital where that care was delivered is also

1 submitting data on that same patient. And so
2 a test would be to cross-reference what's
3 submitted through the physician claim form and
4 the hospital on that patient level.

5 MS. JOSEPH: What you're saying
6 makes sense now and it's clear what you're
7 asking, but that's something that I can look
8 into with our testing team. But I'm not sure
9 that that can happen in the near immediate
10 future. But I can definitely pass that
11 suggestion along.

12 MEMBER SUKO: Okay.

13 MS. JOHNSON: So Karen and Helen,
14 a process question. Where do we go now?

15 DR. BURSTIN: I want to hear
16 Dave's comment first. Then we'll --

17 MS. JOHNSON: Sorry.

18 CO-CHAIR KNOWLTON: I'm not the
19 clinician here but this strikes me -- I have
20 a process question. This strikes me as
21 compared to the robustness of what we
22 considered in the past day and a half this

1 appears like NQF light to me. You know, it
2 just strikes me that we are taking an action
3 that can result in some drastic changes to
4 these measures with nowhere near the depth of
5 consideration that we heard in debate for the
6 past day and a half. And I'm uncomfortable
7 with it.

8 I don't know a lot of the things
9 you're talking about, you're more expert at it
10 than I am, but from where I sit I'm trying to
11 figure this out. It's a little dizzying. Not
12 all the developers have time. They're
13 defending their measures. And I'm saying
14 shouldn't we have the robustness to this
15 process that we had to the other process. I
16 mean, maybe it's a little more work but
17 shouldn't a group look at this and dig in?

18 I mean, I learned a lot in the
19 past day and a half. I'm not learning now and
20 sort of people are winging it. And I don't
21 mean that offensively but people -- my gut
22 reaction, very different level of discipline.

1 And it troubles me because what happens as a
2 result of that, we say okay well this one's
3 gone and this one will stay and we'll split
4 them. I feel like I'm playing Let's Make a
5 Deal, you know.

6 (Laughter)

7 CO-CHAIR KNOWLTON: That I know
8 how to do. So I'm troubled with the process.

9 DR. BURSTIN: I think that's very
10 fair. And you know, the whole concept of
11 doing related and competing is still
12 relatively new, really the last year. I think
13 we were really hearing from the field please
14 stop the cacophony of measures at different
15 levels that aren't harmonized. It drives
16 people insane when they get measures from
17 different health plans and hospitals that tell
18 you your performance is different. So we've
19 really taken this on. But I think those are
20 fair concerns, Dave.

21 And actually what I was going to
22 suggest earlier is I think in some ways the

1 developers have now heard this discussion. I
2 think at this point it should be up to them to
3 talk and bring back a response to the
4 committee that you can read and review in a
5 time period that's not quite as rushed as
6 doing it at this moment.

7 MEMBER KAPINOS: I would have
8 loved to see them at the front end meet up and
9 say hey, we have this common measure here,
10 let's get together and talk about this first
11 before the committee and then we can decide if
12 it's okay or not rather than at the end trying
13 to combine two not necessarily the same
14 measures and try to figure things out.

15 DR. BURSTIN: You're speaking our
16 language, yes. We completely agree and in
17 fact some of you may have heard that NQF is
18 about to pilot a new two-stage endorsement
19 process that would bring measure concepts in
20 first and allow for that harmonization. And
21 then a fully spec'd out, tested measure to
22 follow to try to avoid some of this cacophony.

1 MEMBER WADDY: I just wanted to
2 add that I agree with that. I mean, we don't
3 know the impact of these minor and in some
4 cases major suggestion changes and how that
5 will impact the data that we would see on the
6 final end.

7 MS. JOHNSON: Okay, this has been
8 a great discussion. So I think if no other
9 words on this group let's go onto the next
10 group.

11 And I'm keeping an eye on the
12 clock. I think in some ways the next group of
13 measures will be similar so we might not have
14 to rehash all of the discussion but some of it
15 we definitely will. So if you go to page I
16 guess 5.

17 DR. PACE: So one of the things
18 that we might do, and if you know are these
19 kind of the same issues? Between the same
20 developers? What page is it?

21 DR. BURSTIN: Page 5. Isn't the
22 next measure discharged on? No.

1 DR. PACE: VTE prophylaxis.

2 MS. JOHNSON: I learned yesterday
3 that you're supposed to say VTE, right? Yes.
4 So that is -- I think I am -- I am on page 4
5 of my sheet so I may have a little bit
6 different sheet than you do.

7 Okay. That new document is the
8 actual detailed specs which is a little
9 different than what we looked at yesterday.

10 Okay, so the detailed specs, let's
11 go ahead and start with 0434 and 0371. It is
12 a little different in that 0371 you guys did
13 not look at. That was not one of the measures
14 that you looked at in your project. We did not
15 look at 0371 yesterday when we discussed VTE
16 measures. So, what 0371 is is another measure
17 put forward by Joint Commission and it's not
18 exactly related or competing, but it is -- I'm
19 trying to figure out.

20 DR. BURSTIN: Karen, we could try
21 to make this a little bit easier since we know
22 all these measures. So the biggest

1 distinction here is that, and again the Joint
2 Commission can help here, but the measure
3 0434, the one we talked about was VTE
4 prophylaxis in the setting of stroke. And
5 then there's a broader measure. And my
6 understanding, correct me if I'm wrong, is
7 that that broader measure excludes stroke. Is
8 that correct, Ann?

9 MS. WATT: I apologize. I don't
10 know the NQF numbers. If you could give me
11 the name of the measure that would help. The
12 VTE prophylaxis from the VTE measure set.
13 Could the two be combined, that's the
14 question?

15 CO-CHAIR TIRSCHWELL: I was
16 looking through it and other than that one
17 excludes stroke and one is only stroke I was
18 really hard pressed to find much of a
19 difference.

20 DR. BURSTIN: The PCPI measure I
21 believe is related to surgery.

22 MS. JOHNSON: It's not only

1 surgery, it's a broader measure.

2 MS. WATT: Sorry I didn't bring my
3 sign over too. Even though -- you're right,
4 the measures are very similar. The big
5 difference between the two of them is that two
6 holes is okay for your general non-stroke
7 population whereas that's not true for stroke.
8 And that's the difference basically. Am I
9 right? Yes?

10 MS. JOHNSON: Ramon.

11 MEMBER R. BAUTISTA: I don't mean
12 to be a pain, but I think it's fundamentally
13 unfair to ask us to assess a measure that we
14 looked through yesterday in great detail, in
15 fact to compare to something else that we saw
16 yesterday. So I think it's actually unfair
17 and probably invalid exercise to do this.

18 MS. JOHNSON: Okay, any other
19 comments? Okay, nobody wants to comment
20 further on that. Let's go onto 0240 versus
21 0239 which are related measures. And maybe
22 you would have the same question on this one

1 because 0239 you did not look at in this
2 project.

3 DR. BURSTIN: I actually don't
4 know that they're really that related. I
5 think again it's the same distinction we just
6 talked about. One is for stroke patients and
7 one is for the general population. I think
8 it's the same issue. I don't know that we
9 need to do much more on that at this point.

10 MS. JOHNSON: All right, well then
11 we're going pretty fast here. Then we'll go
12 to 0240 which is the AMA-PCPI measure and
13 comparing that to 0434. Both of those you did
14 look at yesterday in this project. They are
15 competing measures but they are also pretty
16 much it's the same thing that we had earlier
17 which is one is clinician, one is facility.
18 So the third row on the big screen up there,
19 0240 versus 0434.

20 MEMBER KAPLITT: Well, it's the
21 same as the other thing. One is physician and
22 one is hospital. It's the same as what we

1 just did for venous thromboembolism.

2 DR. PACE: We can just ask the
3 same question to the developers on that to
4 come back to you with that.

5 MS. JOHNSON: Okay.

6 MS. WATT: Could I just -- I'm
7 sorry -- make the distinction between the two
8 measures? The 0240, it looks at DVTs only
9 whereas the 0434 looks at DVTs and
10 thromboembolism.

11 DR. BURSTIN: But the prophylaxis
12 is the same.

13 MS. WATT: Okay.

14 MS. JOHNSON: So I guess the
15 developers, we would just ask you to maybe
16 make a response to the committee about whether
17 you think there's a possibility that you could
18 aggregate them differently so that we wouldn't
19 need to -- just give us your opinions on that.
20 Just like we did with the last set. This
21 would be at a later time, not today.

22 MEMBER KAPINOS: If all the

1 evidence that they look at is actually from
2 trials that looked at VTE I think it's just
3 that they did use the wrong term by saying VTE
4 prophylaxis. As I said yesterday the majority
5 of the trials is calling it VTE because what
6 you're really preventing is DVTs and/or PEs.

7 So if actually all the evidence in
8 those trials -- in those two measures are the
9 same then actually it's very simple for the
10 Joint Commission. They should remove every --
11 in all their documents wherever they're saying
12 DVT just change it to VTE and you're fine.

13 MS. JOHNSON: So one extra
14 suggestion, that AMA-PCPI may want to consider
15 renaming their measure. Okay. Any other
16 discussion on this measure group?

17 Okay, let's go onto measure group
18 3, anticoagulant therapy. What we have here
19 is a group of three measures, and the first
20 one 0241 versus 1525. Again, with 1525 that
21 is a measure that you did not consider in this
22 project. It is a measure that is broader I

1 think than the 0241. So the question there is
2 is it necessary to have a separate measure for
3 just the stroke population. And again,
4 perhaps you guys don't feel comfortable making
5 any response on that.

6 MEMBER KAPLITT: I would argue
7 these are -- I mean one is a hospital-based.
8 This is what I was referring to earlier as
9 being totally different. One's a hospital-
10 based and the other one is in the ambulatory
11 clinician's office. So we can start getting
12 into all the little fine details, but it's so
13 fundamentally different that, you know, if we
14 didn't review it I don't see how it's even
15 relevant to try to do that.

16 MS. JOHNSON: So you feel that
17 they're so different that the first question,
18 both are needed and they probably couldn't be
19 combined.

20 MEMBER KAPLITT: Well sure,
21 because one is looking at how patients are,
22 you know, what we reviewed or what's happening

1 to patients who are being discharged, how
2 they're being handled upon discharge. The
3 other one is about general office practice
4 which has nothing to do with that.

5 MS. JOHNSON: Okay. Any other
6 comments?

7 Okay, let's go to the next set,
8 0241 versus 0436. These two you did look at
9 yesterday and they are for the most part the
10 same discussion as we've already had. One is
11 a clinician-level, one is facility-level, both
12 are at discharge. And I think other than the
13 setting the other difference I think might be
14 the definition of having flutter in the
15 numerator. I think that was one difference in
16 terms of potential harmonization. NTIA, thank
17 you. David.

18 CO-CHAIR TIRSCHWELL: I would just
19 comment that again I'd urge the -- one is
20 Joint Commission, right, and one is AMA, to
21 consider harmonization as best possible with
22 these slight changes in definition. And also

1 whether in some brave new world in the future
2 some of the data collection burden could be
3 harmonized so that it only has to be done once
4 through one method, and again be easily
5 divided out to serve both masters.

6 MS. JOHNSON: Any other comments?

7 Okay.

8 MS. JOSEPH: This is Diedra at the
9 AMA. Can I provide a comment about atrial
10 flutter?

11 MS. JOHNSON: Yes. Sure.

12 MS. JOSEPH: Thanks. So the
13 reason why we opted not to include atrial
14 flutter, because we did consider it during the
15 clinical expert panel discussion, is because
16 we use the updated guideline. As you know,
17 our measures are based on guideline
18 recommendations, and we use the updated
19 guideline published in the Journal of the
20 American College of Cardiology. And -- to
21 support the measure.

22 And there was a 1c recommendation

1 referring to atrial flutter. And that
2 recommendation actually was based on expert
3 consensus only and so the clinical expert
4 panel thought that they should only focus on
5 the patient population with the strongest
6 evidence supporting it. So that's why we
7 limited the measure to atrial fibrillation
8 only.

9 MS. JOHNSON: Thank you. Do we
10 have any other comments about this set of
11 measures?

12 Okay, let's go to our last measure
13 group. And this one is the rehab services
14 ordered and assessed from AMA-PCPI and Joint
15 Commission. And again, it's pretty much the
16 same question. One is facility-level, one is
17 clinician-level. And I'm not sure that there
18 are major differences in the definitions here.

19 MEMBER KAPLITT: I mean, they're
20 slightly different, right? Because one of
21 these is the order -- is that it was actually
22 ordered. The other is that the patient was

1 assessed which are not totally equivalent.
2 And there may be value in both. I mean you
3 want to make sure that they're getting
4 ordered, but you also want to make sure that
5 they're getting evaluated. So whether they
6 both have to be captured, I don't know, but
7 you know, I assume if people are getting
8 orders for it without being evaluated that's
9 probably not a good thing. If people are
10 being evaluated and then it doesn't go on to
11 an order that may be okay. So you know, it
12 may be the evaluation is more important, I
13 don't know.

14 MS. JOHNSON: So these are related
15 measures. Is there any issues of
16 harmonization that you guys want to bring
17 forward to ask the developer to respond?
18 Okay, sounds like no. All right, good. So
19 we've gotten through a very difficult session.

20 So I think the last order of
21 business today that we need to talk about is
22 measure gaps. So I know especially yesterday

1 but even somewhat today there was some
2 discussion from many of you on ideas for other
3 measures that perhaps could be considered by
4 developers. So we wanted to open up this time
5 so that if there's any other ideas that you
6 may have that would be great things to measure
7 for quality in the stroke field please bring
8 those to the table now. David.

9 MEMBER HACKNEY: Well, we
10 eliminated the only imaging quality measure we
11 had yesterday and I just would hope that we
12 can get back to that topic. I think there's
13 a lot of important things that could be done.
14 It was more the details of what that one
15 included than it was the principle that the
16 acute imaging is important.

17 MS. JOHNSON: Great. Did you have
18 any like --

19 MEMBER HACKNEY: Suggestions of
20 what it should contain?

21 MS. JOHNSON: Suggestions, yes.

22 MEMBER HACKNEY: I mean, it would

1 get a lot into the details. It might be
2 better to pass on. But I think from the
3 discussion it has to start with something that
4 actually would have an impact on patient care.
5 So it would be how fast was the imaging done,
6 how fast was a reliable interpretation
7 delivered. The time window would have to be
8 appropriate to the time window that's relevant
9 for acute stroke patients, not out to 24
10 hours.

11 It might require capturing things
12 like revisions to a preliminary report. It
13 may or may not want to delve into CT versus MR
14 because it's such a controversial issue, but
15 it could at least provide some guidelines
16 about a minimum imaging study that should be
17 done in the acute case. But I think all of
18 those would be potentially of serious impact
19 to patient care and we ought to ask that to
20 come back with something that's more refined
21 in form about our discussion yesterday.

22 MS. JOHNSON: Thank you for that.

1 Dan.

2 MEMBER LABOVITZ: This may be a
3 question -- well, I'm not sure who would
4 address this. But we're confronted I think
5 with, what we've seen over and over again in
6 the past day and a half is very different data
7 sets some of which are generated by chart
8 review in the hospital and based on what the
9 doctors wrote down interpreted by rules that
10 are sometimes radically different between what
11 doctors think and what coders think.

12 A doctor can write down "Blood
13 cultures positive times 4 bottles" and
14 everybody knows what that means, that patient
15 is septic. And the coder will say "UTI"
16 because their rules are different.

17 MEMBER KAPINOS: -- sepsis is
18 bacteremia.

19 (Laughter)

20 MEMBER LABOVITZ: We face here a
21 problem of -- in the end we generate ICD-9
22 codes and submit data for billing. We submit

1 data for quality review. We submit data for
2 state review. I would suggest that what's
3 never -- what never seems to happen, and
4 there's no attempt to do it is a systematic
5 approach to confirming that what gets reported
6 in say Get With the Guidelines actually
7 matches what gets submitted say to CMS with an
8 ICD-9 code for billing. I think they can be
9 radically different.

10 And what I see in my community, my
11 area, there are hospitals that turn in
12 enormous amounts of billing data and not a
13 whole lot of quality data, but they get gold
14 stars for all their quality. There's a real
15 mismatch there and what I'd love to see is a
16 measure -- some attempt to measure quality
17 reporting to voluntary -- voluntary and
18 quality reporting to say Get With the
19 Guidelines and actual hard data that gets
20 billed for.

21 MS. JOHNSON: Okay, thank you.

22 David?

1 CO-CHAIR TIRSCHWELL: And this
2 partly may demonstrate my ignorance about
3 other quality measures in other areas, but end
4 of life care in stroke is tremendously
5 important. And practicing at a tertiary care
6 place where a lot of our stroke patients die,
7 there's I would say even amongst ourselves
8 there's a tremendous amount of variability in
9 the quantity and quality of care that goes
10 into the dying process.

11 And I don't know, maybe you know,
12 Gail, if measures exist, but I would like to
13 see that sort of play out into the stroke
14 arena more specifically if possible.

15 MEMBER COONEY: There are
16 palliative care measures but I do not believe
17 that there are any that are stroke-specific
18 and that's what I was up for, was to suggest
19 that we develop, you know, given the stroke
20 severity rating the presence or absence of a
21 palliative care consultation. Because
22 currently 85 percent of hospitals have

1 palliative care available in them and that
2 would be one way to approach those end of life
3 issues.

4 MS. JOHNSON: All right. Jane?

5 MEMBER SULLIVAN: In part in
6 response to the -- what happened with the
7 speech-language pathology measures and in part
8 from where I sit as a physical therapist I'm
9 really interested in functional outcome
10 measures, both positive and adverse like falls
11 data, those kinds of things. So I'm not sure
12 where that is in regards to this process, but
13 I'd really like to see some attention
14 especially looking at stroke severity relative
15 to functional outcome.

16 DR. BURSTIN: -- just mention that
17 we're doing a meeting at the end of July
18 actually that Karen's leading focused on the
19 methodologic issues and looking at delta as
20 function, for example, and other patient-
21 reported outcomes. There's a lot more that
22 needs to happen there but there's a lot of

1 methods that really need to get cleared up
2 first.

3 MS. JOHNSON: Gregory?

4 MEMBER KAPINOS: I want to support
5 the idea of Dr. Labovitz. It was really
6 enlightening to come here and see that
7 actually all the data that were based on these
8 -- from billing and coding which is sometimes
9 not perfectly accurate.

10 The other idea that I think I
11 shared with Dr. Tirschwell yesterday was once
12 those measures are in effect and we collect
13 just a rate or 90 percent of our patients are
14 getting, for instance, antithrombotics upon
15 discharge I think that this absolute value
16 should be actually weighted with the fact that
17 some hospitals will exclude a lot of their
18 patients.

19 So as we were discussing
20 yesterday, when you read for instance a
21 randomized clinical trial you have a flow
22 chart that tells you how many patients were

1 excluded, then how many patients met the
2 inclusion criteria, and then they were
3 randomized into the two arms. For your
4 absolute number -- so I would -- what I want
5 to get to is hospital A is not necessarily
6 better than hospital B because their score is
7 92 percent versus 90 percent, if actually
8 hospital A excluded 90 percent of their ER
9 visits for stroke for instance. So maybe we
10 should actually look at the number of
11 exclusion of patients as a way to weighing the
12 score. So that 92 multiplied by 50 percent of
13 exclusion comes up to a new score that is
14 actually more valid to compare to hospitals.

15 Because otherwise, as I said, I
16 think a lot of hospitals could have a tendency
17 to exclude a lot of their patients so that 90
18 percent compliance to antithrombotic for
19 instance is actually generated on a very small
20 percentage of their actual patients. So I
21 think NQF should revisit the issue of that
22 absolute value and maybe create a more complex

1 system looking at the exclusion.

2 CO-CHAIR TIRSCHWELL: Can I
3 respond to that just briefly? Because I
4 slightly objected to that suggestion yesterday
5 because I think that different hospitals will
6 have different appropriate exclusion levels.
7 And so the hospital with the more complicated
8 patients and the more appropriate exclusions
9 in that system would be counted against.

10 And you know, it costs a lot of
11 money and I suggested that Greg start a
12 company to do this, but validating the
13 exclusions, external validation of the
14 exclusions would be an extremely interesting
15 point. And I think there would be some
16 shocking discoveries potentially, although
17 hopefully in only a small number of hospitals.
18 And I do have a couple other points but I
19 think --

20 MS. JOHNSON: I think Anna was
21 next in line.

22 MEMBER BARRETT: Thanks. Nobody's

1 going to be surprised to hear me say that we
2 shot down our only rehabilitation measures so
3 both outcome and process measures in
4 rehabilitation given the amount of funds.

5 I started my career in the VA, or
6 I was trained in the VA and they at least
7 always say, you know, rehabilitation gets this
8 much of our budget because that's so much of
9 the person's life and expenses, and here's the
10 amount that we put into research and all the
11 acute care stuff. Well, that can take care of
12 itself.

13 Lastly, I would also say that
14 hidden health disparities play a large role
15 both at the quality of care -- quality care we
16 hope identifies hidden disabilities after
17 stroke or non-motor disabilities. After
18 Parkinson's disease non-motor became such a
19 buzzword that we can talk about it in stroke
20 as well.

21 But as we're talking about a lot
22 of measures one has to have communication

1 ability, one has to have appropriate ability
2 to interact with the physician in order to
3 participate even in the measure, and then of
4 course falls, medication adherence, and a
5 number of safety measures are determined by
6 hidden disabilities.

7 MS. JOHNSON: Michael.

8 MEMBER KAPLITT: I would just ask
9 NQF for the next phase or round or whatever if
10 we could in advance have some sort of a
11 summary of other measures that we haven't
12 evaluated that are already endorsed in this
13 area.

14 For example, the radiology
15 question, yesterday we were told that there
16 actually is a measure in terms of the speed
17 with which a radiologist reads the film or
18 something like that. So having a summary of
19 all those, not the whole extensive thing, but
20 just maybe the title, the inclusion/exclusion
21 -- I mean, the numerator, denominator and
22 exclusion criteria, just the fundamentals

1 summarized in a table in advance would help
2 with this kind of discussion I think.

3 MS. JOHNSON: Thank you. David?

4 CO-CHAIR TIRSCHWELL: So, two
5 comments and these are more I think process
6 suggestions for NQF. So, I feel bad about all
7 those speech pathology measures that went
8 down. And I think that a pre-review process
9 potentially with NQF staff to identify a
10 weakness in our application without actually
11 changing any of the truth behind it all could
12 have prevented that. And so I don't know that
13 you have the manpower to do this but I think
14 that it would make sense.

15 And quite honestly, you know,
16 there were all these updates to the forms
17 after the conference calls, but maybe the
18 first set of updates should be before you show
19 the applications to us so that they're in
20 better shape when they get to us. There were
21 some real weaknesses in some of the original
22 applications that I looked at too, so

1 something for you to consider.

2 And then as far as the competing
3 and harmonizing related measures I think as
4 you guys probably noted today, I think the way
5 we have this really structured approach to
6 identifying and voting, I think you need to
7 create a little more process around that
8 discussion to help organize the way things go.

9 MS. JOHNSON: Did Helen or Karen
10 have any response to those before we go on?

11 DR. PACE: Yes, just, you know,
12 the pre-review is something we've identified
13 and we're actually piloting some processes to
14 do that. Because it is a consistent issue of
15 the quality of the application itself. And
16 you know, right now our time lines don't allow
17 that which has been a problem so it kind of
18 repeats and repeats. So we are pilot testing
19 doing some of that. We agree that it would be
20 helpful.

21 MS. JOHNSON: Bill.

22 MEMBER BARSAN: This may reflect

1 some of my ignorance about how the process is
2 carried out because this is the first time
3 I've been involved with NQF, but are you
4 mostly passive in terms of waiting for people
5 to come to you for things, or do you actually
6 go out and solicit new things? I mean, I
7 would suggest that if you don't it would be --
8 like for example, some of the suggestions we
9 made, will you go out and try to get people,
10 solicit people to turn those in?

11 DR. BURSTIN: Right. So we try as
12 best we can to go out there, let people know
13 projects are upcoming. Part of what we've
14 tried to do moving forward is actually having
15 a schedule for when projects will come up at
16 a regular basis. So the field is just on
17 notice when they can submit at various points
18 in time.

19 The hardest thing actually frankly
20 is that there is a limited amount of money out
21 there for measure development. And so I think
22 the challenge is taking some of the great work

1 emerging out of research and trying to
2 translate some of that into measurement.

3 But yes, I mean anything you guys
4 could do particularly before this next round
5 of measures to kind of let people know out
6 there that there is an open call for measures,
7 we'd love to get stuff in.

8 Again, the other thing I pointed
9 out is I think there's still a lot of effort
10 being made around the similar set of measures.
11 And we haven't -- I think we're hoping to see
12 more that kind of takes us to a very different
13 level.

14 MS. JOHNSON: And a plug for next
15 phase. We do not at this point have any TBI
16 measures in our pipeline nor do we have any
17 migraine or headache measures. So if you guys
18 know of any folks who are working in that area
19 please publicize the call for measures.

20 MEMBER WADDY: I was wondering is
21 there any data on how much cost gets added by
22 having these types of measures as well as --

1 so really what's the burden to the hospitals
2 as well as what's the overall impact and how
3 much do they change things?

4 DR. BURSTIN: It's very variable
5 depending on the kind of measure. Obviously
6 when measures are completely claims-based
7 outside the hospital that actual collection of
8 data is not something that's a burden on the
9 hospital but still is in terms of reacting and
10 kind of improving around it we hope is a
11 significant part of it.

12 We for awhile there actually were
13 asking developers to let us know how long it
14 took to collect the data, the costs of it.
15 Just, it's so not comparable across measures
16 that we don't go there anymore.

17 In terms of impact it's the right
18 question to ask and actually we just recently
19 updated our usability criteria that'll go
20 forward in the fall I guess which is much more
21 explicit about use and usefulness. So, what
22 is the use for the measure and what is the

1 evidence that it has either improved care or
2 evidence of unintended consequences. So I
3 think we've tried to make that more crisp
4 because I think committees have told us at
5 least to date it's not very crisp.

6 MEMBER WADDY: I think that would
7 be very interesting, particularly in measures
8 that were pretty close to that threshold such
9 as the antithrombotic use and that 2 to 5
10 percent, that could weigh into how much of a -
11 - we think an impact can actually be made
12 which hopefully there's a great impact.

13 DR. PACE: And I think your
14 question of cost also gets at one of the
15 drivers behind the interest in harmonization
16 and competing measures. Because it just adds
17 burden, but the difficulty as you saw is that
18 at this point you all get measures, NQF gets
19 measures that developers have already invested
20 time and resources into. And so it's, you
21 know, we keep trying to move it upstream, like
22 have those discussions before you come to NQF.

1 To date that hasn't been real successful and
2 we're going to be looking at -- and any
3 suggestions on that would be welcome, but
4 looking at how to continue to push on that.

5 MS. JOHNSON: We're getting very
6 close to our time. I think Risha definitely
7 had her hand up, and then Jane, and Dave? Oh,
8 Dave, okay. All right. Risha?

9 MEMBER GIDWANI: Thanks. First
10 off I just want to say I think this is a
11 really thorough and systematic and well-
12 organized process, so thank you, NQF. I am
13 really happy I was able to be a part of this.

14 I have a couple of suggestions for
15 the next go-around and that's that if there
16 are measures that are outcome-based and that
17 have already been endorsed I would suggest
18 that it be a requirement that the developer
19 show the data since the last few periods of
20 time so that we are able to really assess the
21 impact of these standards. And then the other
22 suggestion that I have is, you know, just to

1 respectfully suggest that there be a couple of
2 folks with expertise in risk adjustment
3 statistics or economics if there are going to
4 be risk-adjusted outcomes that are going to be
5 evaluated. Risk adjustment is a very
6 sophisticated field, it's also relatively new
7 and it's fraught with a lot of complexities.
8 And I in no means wish to say that we
9 shouldn't be engaging in it, in fact just the
10 opposite, I think we should certainly be
11 trying to help move the field forward. But
12 statistics is a science that has a strong
13 element of an art to it, and so I think that
14 it's just like in any academic or intellectual
15 enterprise, it's worthwhile to have a few
16 different folks with expertise at the table so
17 that we can make sure we're engaging in strong
18 intellectual debate. Thank you.

19 MS. JOHNSON: Jane?

20 MEMBER SULLIVAN: Not to beat a
21 dead horse but I want to go back to the speech
22 measures and the work group. And I think

1 maybe a suggestion. I think during the work
2 group call the group was concerned about the
3 level of evidence. And we were given some
4 guidance to use our clinical judgment as well
5 as the very limited information that was
6 presented by the developer. And that seems
7 like it was a little different than what
8 happened here. And so just further
9 clarification on what the threshold is, what
10 the bar is for the outcome measures. I think
11 that would be very, very helpful in the
12 future.

13 And I also, I sort of echo your
14 concern about what happens with the
15 suggestions or the queries that the work group
16 make of the developers because I believe that
17 there were some queries made in our work group
18 call that we didn't see addressed. And I
19 think that might have helped and might have
20 resulted in a different outcome at this level.

21 MS. JOHNSON: Thank you. David.

22 MEMBER HACKNEY: Echoing what

1 other people have said, I got the impression
2 a lot of the developers were surprised by the
3 number of questions about evidence of impact.
4 And I'm not sure they were devoting nearly as
5 much attention to that issue as we were. And
6 I think better communication about what we are
7 looking for could have prepared them to
8 present the sort of information that we said
9 was essential without which we weren't moving
10 forward.

11 MS. JOHNSON: Okay, any other
12 comments?

13 CO-CHAIR KNOWLTON: Never sit
14 beside someone who's supposed to call on
15 folks. I don't know how to measure this.
16 Again, a lot of it's colored by my own
17 experience. But we have no measure of pre-
18 hospital care. We all agree it's critical.
19 States that have an integrated stroke system
20 and stroke code system have integrated pre-
21 hospital care. I was the beneficiary of that
22 in Connecticut. And it's made an, I believe,

1 an amazing difference in outcome. And yet we
2 don't -- so I don't know who to measure this.

3 And you guys, particularly you
4 clinicians are a lot more adept at how you
5 could measure that. But it's such an obvious
6 gap to me that we're not looking at some way
7 to capture that. And I do believe it makes
8 the difference between being functional or
9 being in a SNF unit.

10 MS. JOHNSON: Michael? Sorry,
11 Salina.

12 MEMBER WADDY: Or actually, I
13 mean, post-hospital care in terms of being
14 sure not only that the patients receive their
15 antithrombotic prescription or their statin
16 prescription, but whether or not they're
17 actually in control some reasonable amount of
18 time, 3 months, 6 months, whatever you want to
19 choose. And I think that that's extremely
20 important as well. And we do a horrible job
21 at that.

22 MS. JOHNSON: Bill?

1 MEMBER BARSAN: Let me just --
2 hospital care thing. So, pre-hospital care is
3 a quagmire for trying to decide anything
4 because knowing where the responsible people
5 are if you're going to measure quality, who is
6 responsible, it's tremendously variable by
7 state, by city. I mean there's really no --
8 you have volunteer squads, you have fire
9 department squads, you have, you know, non-
10 profit foundations and all kinds of stuff.
11 And they deliver to so many different
12 hospitals that it's not any one hospital
13 that's responsible, or one group of physicians
14 even that you can say well you're the ones
15 that are supposed to be doing that. And so
16 it's a really difficult area to work with.

17 I mean, just trying to make sure
18 that all your pre-hospital providers do a pre-
19 hospital stroke scale is very, very difficult.
20 Some of them you can, some of them you can't.
21 But I agree with you, there's the need for
22 that, there's no question.

1 CO-CHAIR KNOWLTON: If you measure
2 it you can manage it.

3 MEMBER KAPLITT: Well, the ones
4 you could measure. It's a good point. I
5 mean, you can measure simple things to see how
6 you're doing. Instead of measuring to lay
7 blame you can measure to see how you're doing,
8 right? Like the number of patients that get
9 transferred from one hospital to another, you
10 know.

11 I mean, you have a setup in
12 various states where you're supposed to do
13 certain things, but that doesn't mean the
14 patients are winding up there. That's true in
15 a lot of areas like TBI and other things. So
16 you could measure the number of patients that
17 would have been candidates let's say for some
18 intervention like t-PA but were delayed
19 because they didn't go to a stroke center,
20 let's say, right? And then that would give
21 you an idea of how you're doing. And then you
22 could measure it by community to see. So you

1 may not blame anybody, but let's say one area
2 of a state is much worse than other areas.
3 Then they know that they've got a problem with
4 their local whatever, emergency response or
5 something. So, I mean there are some metrics
6 I think that could be incorporated.

7 I don't think you're ever, you're
8 right, going to get to the level of individual
9 physicians or individual institutions.

10 CO-CHAIR KNOWLTON: I bring it up
11 because every neurologist or ER doc I've
12 talked to agrees it's a critical factor.
13 Everybody agrees it is a quagmire. In my own
14 experience it happened in Connecticut because
15 Yale took charge and said we're going to set
16 up a stroke code. That's what happened. And
17 they set up stat centers. And my time from a
18 911 call to my head in a CAT scan was 21
19 minutes and I was driving on the Connecticut
20 Turnpike at the time of the stroke. And then
21 was transferred by ambulance to Yale 15 miles
22 away and I still had an hour and a half left

1 on the stroke clock. You know, that was an
2 integrated delivery system and it was
3 incredible.

4 So, but it was called as a code,
5 it was a stroke code. And so it was run like
6 -- I have a background in EMS. I was a
7 firefighter and I can tell you that when
8 things get called codes they act in different
9 ways because it's a firm protocol. And it just
10 strikes me that something that everybody seems
11 to agree has so much to do with outcome and we
12 don't measure it. So I agree with Michael's
13 addition that we've got to measure it. I also
14 know it's very difficult. I mean it is very
15 difficult.

16 MEMBER BARSAN: You can measure
17 it, the problem is who do you hold
18 accountable. That's the difficult part.

19 CO-CHAIR KNOWLTON: Well, maybe at
20 a starting measure it's not, like Michael
21 said, it's not seeking to blame, it's saying
22 how are we doing, you know, and that's the

1 first step to doing it. But I just notice
2 that it's -- I've never seen it. I raised
3 this at the end of the last stroke session
4 saying that this ought to be --

5 MEMBER BARSAN: I mean, do you all
6 -- are there any measures at NQF that have
7 anything to do with pre-hospital care? Like
8 with MI or anything else? Pre-hospital EKGs,
9 anything like that?

10 DR. BURSTIN: No. But we have
11 been doing some work for ASPR, the Assistant
12 Secretary for Public Health Responsiveness --
13 I always forget exactly what the acronym is --
14 that does emergency preparedness and actually
15 tried to do an environmental scan for them of
16 what measures are out there around crowding
17 and diversion and some of the sort of systemic
18 issues I think that might lead to some of
19 this. There's very little out there. So
20 we're continuing to see what could be
21 developed in that space.

22 And again, some of those are

1 really intended to assess a region, to go to
2 Michael's point, as opposed to a doc or an EMT
3 service, that at least if you start getting
4 data at your region you can kind of, again,
5 drill down to figure out where you can make a
6 difference. But maybe we'll get you on that
7 extra panel.

8 MEMBER BARSAN: Well, the biggest
9 question is who do you even ask. Who gets the
10 data? Where does the data come from? That's
11 a real fundamental question which will be very
12 difficult.

13 CO-CHAIR KNOWLTON: Well, that's -
14 - thing about pre-hospital care, especially as
15 it activates the EMS system is there's a lot
16 of data. Because the call comes in, it
17 punches in, it's time-stamped. Arrival is
18 time-stamped. So there's a lot of data. They
19 don't do anything with it but it's a lot of
20 data because all that stuff is legal stuff.

21 MEMBER WADDY: There's a lot of
22 data for only part of the country largely

1 because there are huge swaths which is
2 actually a health disparities issue of the
3 country where there is no EMS system and it's
4 completely disorganized.

5 MS. JOHNSON: Okay, and Bill, your
6 card is down. All right. And Mary.

7 MEMBER VAN DE KAMP: I had one
8 thing to add. What made me think of that,
9 David, was your comment. And that is that I
10 think it's culturally something we need to
11 embrace more and that's to look at the quality
12 for the improvement of quality rather than the
13 fear of penalty of being the lower half. And
14 I know that's not this group because this is
15 the best of the best, but I think as move
16 forward that's where quality I think is. And
17 I don't know if pay-for-performance ends in
18 coming into that impact but I think it is
19 difficult.

20 As people look to be measured it's
21 the fear of being measured as poor without the
22 right measurement, rather than trying to look

1 at what we may measure could improve quality.
2 And so just a comment on, as we go forward,
3 how we sort of think about measuring quality.
4 And the first response is did we do something
5 wrong.

6 MEMBER WADDY: That's why I think
7 it would be very helpful to have information
8 on how hospital practices or physician
9 practices have actually responded so that, you
10 know, potentially we can even look back
11 through measures, measures that may not have
12 really made a difference in quality but
13 certainly may be burdensome. But there may be
14 other measures and how were those developed so
15 that they actually led to our overall goal,
16 that it's not just a measurement process that
17 we want to go through but an improvement in
18 quality.

19 MEMBER KAPINOS: I think Dr.
20 Knowlton would say that. But earlier on when
21 you talked about the lack of rigor for this
22 process of this afternoon compared to earlier,

1 I thought you would have suggested so I'm
2 going to do it now. Why don't we just go
3 through the -- everybody work through the
4 algorithm that you presented on the PowerPoint
5 and you vote for each step? Rather than just
6 put the PowerPoint there and then we all
7 chatted about are we harmonizing or not. So
8 I think we should all work through that
9 algorithm that you put and vote for each step.
10 That would be more rigorous than just a
11 discussion for the harmonization process.

12 MS. JOHNSON: Okay. When we got
13 you guys going you really came up with several
14 avenues for potential measure development. Is
15 that everything for now? I mean there's
16 always going to be time for you to add things.

17 Okay, now we need to open up the
18 meeting one last time for any public comments.
19 So Operator, would you open the lines for any
20 public comments? Operator?

21 OPERATOR: At this time in order
22 to ask a question press * then the number 1 on

1 your telephone keypad. At this time there are
2 no questions.

3 MS. JOHNSON: Thank you. So now
4 we're going to turn it over to Suzanne who
5 will tell us our next steps.

6 MS. THEBERGE: Okay. First of all
7 on behalf of the project team I just want to
8 say thank you so much for all your time the
9 last few weeks. We really appreciate it and
10 this has been an excellent meeting. We've
11 done an enormous amount of work.

12 So I just wanted to go over the
13 next steps both in our process and for you.
14 NQF staff are going to put together a draft
15 report over the next couple of weeks and we'll
16 send it to you before we post it. But it will
17 go up online we're estimating July 13th for
18 public comment.

19 And during that time people will
20 have the opportunity to comment on the
21 measures that were submitted, on your
22 decisions, raise any issues that were not

1 raised, et cetera. That's a 30-day period and
2 following that, that closes in mid-August.

3 Then we give the developers a
4 chance to respond to the comments on their
5 measures and we'll also give you guys some
6 time to look at the comments that came in.
7 And then we'll have a call at the end of
8 August to discuss all the comments, see --
9 there may be responses that you need to draft.
10 There may be measures that you need to re-vote
11 on based on new information, et cetera.

12 And then we go into the voting
13 which we're estimating to start in mid-
14 September. So NQF membership will vote on
15 whether or not to recommend the measures for
16 endorsement. And then the measures following
17 that go to our Consensus Standards Approval
18 Committee and our board for final
19 ratification.

20 As you know, we will be starting
21 our phase 2 of this project. We'll be sending
22 out a survey in July to see if you're still

1 available for phase 2. We may need to make
2 some changes to the committee based on
3 people's availability, making sure we have
4 different sets of experts because we're going
5 to be looking at other neurological conditions
6 besides stroke. So we want to make sure we
7 have dementia experts, stuff like that.

8 We're going to be looking at
9 dementia, delirium, Parkinson's, epilepsy and
10 whatever else comes in. So again, if you know
11 of measures that would fit into those
12 categories please let us know or let the
13 developers know about our call.

14 And we're closing that call for
15 measures July 13th also and then we're going
16 to send them to you all right after Labor Day
17 to begin that review process. And we're
18 looking at work group calls in mid-September
19 and then our steering committee meeting is
20 October 3rd and 4th. So I'll follow up with
21 you all by email later this summer to assess
22 your availability and everything, but just

1 keep that in mind. You'll be getting another
2 batch of measures at the end of the summer.

3 And are there any questions?

4 Okay, that's all the next steps.

5 MS. JOHNSON: Thank you guys.

6 CO-CHAIR KNOWLTON: Thank you all.

7 It's a great group, great session.

8 DR. BURSTIN: Thanks, everybody.

9 Thanks to the Davids.

10 (Whereupon, the foregoing matter
11 went off the record at 3:11 p.m.)

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A					
AAN 259:17 260:17 263:19	academic 382:14	180:18 213:21 295:22	265:14 270:13 271:1 275:15 280:10 292:11 305:8 317:5 366:4	197:1 199:10,14 291:22 292:18 300:13 307:18 308:5 309:18,20 310:9,11 314:11 382:2,5	
AAN's 262:7 263:18	Academy 3:19 259:14 309:17	acknowledgment 183:12	addressed 19:8 237:4 260:16 278:22 383:18	adjustments 296:15	
Abandoning 337:9	accept 75:20 78:3 287:6	acronym 390:13	addressing 13:18 14:15 140:21 243:7 260:2 262:6	adjustment's 175:11	
ability 33:14 38:3,7 42:21 47:15 106:9 106:19 107:16 138:12 143:13 153:15 160:1 161:1,9 223:11 310:11,19 374:1,1	acceptability 27:13 93:22 117:9 275:6	act 283:4 389:8	adds 101:15 380:16	ADLs 247:3,3	
able 20:16 33:1 36:16,22 37:6 56:22 77:18 79:10 79:18 85:10 132:20,22 133:18 160:15 171:2 173:12 179:7,8 189:18 194:16 197:3 218:13 242:5 300:10 316:11 317:20 335:6 338:1 339:7 339:9 346:7 381:13,20	acceptable 77:2	action 349:2	adept 385:4	administrative 23:5 25:7 29:9 40:19 51:8 70:6 82:16 87:16 88:6 88:10,14 89:15 94:9 95:20 99:20 108:3 115:13 119:20 123:15 133:6 161:19 164:15 191:4 260:7 307:10 346:13 347:8	
absorb 277:7	accepted 21:17	activate 38:5 92:9 185:8	adequate 10:2 15:15 22:13 86:18 99:5 100:7 199:14	administratively 251:8 258:19	
absence 121:14 191:17 222:7,18 368:20	accepting 150:20	activities 223:12	adequately 83:12 87:9 166:6 291:21	administrative-b... 96:11 106:6	
absolute 67:7 217:11 370:15 371:4,22	access 36:10,17 73:6 147:17 327:1	actual 31:19 157:1 157:9 208:13 279:20 319:11 327:14 353:8 367:19 371:20 379:7	adherence 158:13 374:4	administrator 177:10	
absolutely 125:4 253:11 297:6 305:18	accommodate 304:9 335:17,20	acute 4:5,6,8 23:2 23:13 29:17 47:20 90:4,9,14,22 112:7 122:7,14 123:2 131:1 305:15 306:5 364:16 365:9,17 373:11	adjust 99:13 107:14 116:10 141:16 165:11,12 166:21 170:18 192:17 263:10 308:2	administrators 194:16	
absorbing 107:7,20	account 37:1 77:18 77:20 85:16 87:14 91:8 115:7,10 155:10 260:10 324:3	add 35:7 60:4 76:11 136:3,6 138:15,17 142:14 182:19 202:15 203:22 210:10 267:15 286:16 334:2 343:15 345:4 352:2 392:8 394:16	adjusted 86:14 122:17 320:15	admission 32:3,7 39:5 54:17 67:21 68:3,6 90:8 98:10 98:12 99:3,15 112:7 145:22 148:13 150:18 165:13 166:22 170:16 174:3,7,15 175:12 196:1 292:21 307:12 314:8,10	
abstract 278:19	accountability 8:18 76:14 77:3,10 153:11 260:19 342:10,12	added 86:11 166:12 378:21	adjuster 99:16	admirable 71:21	
abstracted 40:1 45:20 109:5 181:20,22	accountable 86:4 389:18	addition 8:19 53:9 389:13	adjusters 98:11 99:2 101:9	adjustment 4:3 5:21 7:10 8:1,6,12 9:10,15 11:11,19 14:14 21:5,18 28:20 29:20 30:21 34:10 41:11,19,21 43:1,5 53:2 85:2,9 86:12 88:4 90:11 91:4,5 96:7 99:7 116:20 121:15 125:9 128:15 138:18 140:14,18 152:4,5,6 170:15 175:12 191:18	admissions 33:22 122:21 314:7
abstracting 110:6 346:21	accounted 46:16 52:9 115:3 142:7 149:15 150:9 152:15	additional 4:19 29:12 47:2 96:1 194:2,5 197:4 202:12 299:7 302:7 308:10 341:19	adjusting 117:1 138:20 163:5 262:17 263:5,7	admit 81:19	
abstraction 29:10 278:17 319:16	accounting 37:4 152:8 160:4	address 8:6 11:13 11:22 12:4 63:4 68:4 211:12	adjusted 86:14 122:17 320:15	admitted 49:18	
abysmal 150:4	accuracy 341:11				
	accurate 321:16 327:14 370:9				
	accurately 263:15				
	achieve 88:14 316:5,6 334:11				
	achieved 88:7				
	achieving 17:12 207:17				
	acknowledge				

86:3,10 90:22 113:18 171:21 190:5,9 305:18 313:20 admonished 176:1 adopts 179:10 adults 151:18 288:16 309:9 advance 38:12 374:10 375:1 advanced 92:20 advantage 88:21 advantages 176:13 adverse 92:18 170:17 369:10 advice 90:19 123:8 advocate 298:16 342:5 advocating 334:22 335:1 affect 59:21 143:14 153:15 158:9 168:6,18 175:1 182:22 183:4,16 210:18 211:6 214:12,13 217:16 236:16 244:7 279:1,2 281:11 282:18 afford 37:20 afraid 33:22 240:10 African-American 126:12 African-America... 323:10 afternoon 15:20 264:3,21 393:22 age 23:16 30:2 92:16,20 267:22 288:4 298:22 301:15,16 303:11 304:10 310:15,19 311:2,9,11,14,16 312:3,7 aged 122:15 agencies 25:9 47:14	75:13 153:12 Agency 3:4 24:13 24:16 75:1 agenda 5:10 264:1 agents 322:3 ages 93:3,3 288:3 308:22 aggregate 100:6 101:8 105:14 145:1 357:18 aggregated 342:3 aggregation 269:5 aggressive 55:8,9 aggressivity 55:11 ago 105:13 172:12 173:20 193:6,22 194:9 217:19 agree 40:6 49:2 63:8 80:20 111:18 132:18 133:20 141:6,17 153:18 162:22 208:11 223:5 241:19 242:1 253:7 258:1 258:10 291:2 299:9 300:5 301:12 306:19 330:22 331:8 332:19 336:4,22 343:6 351:16 352:2 376:19 384:18 386:21 389:11,12 agreed 26:11 228:22 231:16 agreeing 331:10 agreement 18:15 25:18 34:8 94:7 213:21 307:1 agrees 251:5 257:6 388:12,13 ahead 22:18 63:6 69:19 77:13 78:18 84:4 91:19,20 92:9,9 93:17 94:13 107:1 108:7 109:1 118:13	119:10 120:14,21 121:20 124:1,15 127:5,5,16,17 142:1 143:21 162:9 169:5 191:21 205:3 215:6 223:2,14 236:4 250:18 292:13 295:9 305:9 321:4 326:17 353:11 AHRQ 12:16 13:12 14:11 18:15 21:4 23:4 34:8 45:15 62:20 64:14 65:5 65:19 66:3 74:20 75:14 280:15 281:5 285:4 299:13 300:15 301:7,21 304:16 307:9 308:20 310:1,14 311:1 aiming 87:9 airplane 139:18 algorithm 276:12 394:4,9 aligned 265:19 314:14 alignment 304:19 alive 90:19 123:8 246:9 alleviating 71:22 allow 39:16 110:2 128:22 138:13 257:15 299:15 351:20 376:16 allows 85:16 87:22 91:8 302:4 345:17 alluded 293:21 all-cause 4:5,7 85:6 90:3 122:6,17 131:8 157:22 188:17 189:2 all-or-none 319:11 all-patient 30:5 altered 102:21 alternate 235:15	alternative 73:7 AMA 337:15,21 347:10 360:20 361:9 amazing 45:14 86:7 385:1 AMA-PCPI 3:9,12 327:22 328:8 340:11 346:19 356:12 358:14 362:14 ambulance 388:21 ambulatory 359:10 America 269:9 American 3:1,17 3:19,21 40:9 193:1 239:15 259:14 309:17 361:20 AMI 287:11 amount 45:18 83:6 121:8 123:11 134:16 186:15 217:19 368:8 373:4,10 377:20 385:17 395:11 amounts 367:12 Amy 149:9 analyses 186:9 296:3 302:7 analysis 10:7 16:3 19:17 41:5 42:20 44:22 47:18 123:13 139:2 169:16 199:12 267:8 284:12 292:18 293:17 296:4 328:6 Analyst 2:21 analytic 24:18 292:16 analyze 316:13 ancillary 167:11,14 168:10 and/or 53:5 358:6 anecdotal 181:5 aneurysm 104:18	301:3 Ann 2:14 3:20 316:18 335:22 354:8 Anna 372:20 annoying 346:17 annual 35:5 65:12 answer 47:4 55:14 58:8 152:3 177:10 182:6 218:22 220:2 221:11,15 271:13 316:20,20 321:3 answered 28:4 30:15 83:4,12 146:4 329:11 answering 119:3 answers 119:6 200:7 209:12 224:14 answer's 271:13 antibiotic 171:21 anticoagulant 358:18 antithrombotic 140:2 315:3,4 317:9,13,14 320:11,17 321:7,9 321:17 322:3 328:3 333:21 371:18 380:9 385:15 antithrombotics 338:13 341:8,14 370:14 ANTMAN 3:1 anxiety 296:11 anybody 32:14 34:21 70:12 79:11 142:10 161:4 252:5,15 279:19 288:13 334:6 388:1 anymore 119:8 139:18 190:2 327:18 379:16 anytime 84:5
---	--	---	--	---

anyway 76:4 141:17 188:5 320:14	13:3 14:8 40:2 128:19 185:4 245:6 256:17 263:9 308:2 313:13 337:8 367:5 369:2 376:5	208:6 211:14,20 211:22 212:7 215:2 218:12 230:13 326:9 367:11 374:13 378:18 386:16 388:1	aspect 35:9 91:12 164:7 aspects 35:2 78:14 128:21 129:6 aspiration 175:8 aspirin 317:11 320:8 321:11 322:8,18 323:2,5 323:11 327:5,10 327:13,17 aspiring 323:1 ASPR 390:11 assertion 34:18 assess 85:10 87:9 123:11 137:15,16 165:19 174:6 175:13 194:16 229:6 257:11 263:15 277:1 355:13 381:20 391:1 397:21 assessed 204:4 253:13 362:14 363:1 assesses 86:12 assessing 88:19 105:15 140:17 207:4 assessment 95:9 229:10 253:6,10 254:16,17 257:8 257:10,13,19 268:4,5,21,21 assigned 36:8,18 Assistant 390:11 associated 10:10,17 10:21 15:5,11 16:2 32:16 38:16 92:19 115:21 158:11 171:13 211:8 253:16 association 3:2,17 3:21 40:10 64:19 193:2 239:9 assume 222:17 310:6 363:7 assuming 217:1	assumption 77:9 143:10 155:3 assumptions 12:5 astray 330:17 atrial 361:9,13 362:1,7 attached 72:15 attack 25:4 293:2 337:3 attempt 150:16 367:4,16 attempting 135:12 attention 4:17 158:20 369:13 384:5 attributable 87:13 attributed 123:4 305:16 313:19,21 attribution 305:22 audit 157:3 audits 322:21 augmentative 235:15 August 396:8 AUSTIN 1:20 automatically 287:6 availability 158:15 277:11 397:3,22 available 30:4 36:19 54:4 82:15 96:6 159:7 181:10 194:15 276:10,15 276:16,20 298:21 298:22 369:1 397:1 avenues 394:14 average 14:1 28:1 126:17 188:10 254:4 Averill 34:15,20 avoid 306:1 351:22 aware 8:17 12:20 36:16 64:2,4,8 204:22 awhile 277:13 336:18 379:12
apart 147:5 155:17 aphasia 206:22 215:15 252:1 294:12 aphasic 206:20 207:7,8 apologize 84:22 202:6 354:9 apparent 292:21 appear 99:14 137:4 appearance 72:17 appears 79:3 215:15 349:1 applaud 337:15 apples 329:5 applicability 16:13 275:21 277:9 289:7 341:5,18 applicable 15:22 303:18 application 25:7 76:21 77:5 118:4 230:8 252:10 253:7 275:15 375:10 376:15 applications 8:19 8:21 76:17 77:3 77:11 375:19,22 applied 36:4 169:19 170:6 applies 60:1 90:5 apply 8:21 21:5 38:12 60:1,3 225:14 251:8 290:3 applying 337:10 appointments 172:3 appreciate 7:14 34:17 36:12 169:4 169:8 395:9 appreciation 135:5 171:11 approach 8:8 12:9	approached 237:14 approaches 8:1,2 8:12 11:11 12:2 12:18,19 13:13 14:17 16:18 17:10 172:9 appropriate 9:14 11:22 15:14 21:16 113:9 128:17,19 142:9 174:16 199:2 205:18 211:12 218:18 256:21 257:16 263:12 269:6 296:21 318:18 320:3,10,13 329:13 330:5 332:19 365:8 372:6,8 374:1 appropriately 167:17 appropriateness 318:16,22 approval 6:9 51:10 396:17 approve 331:19 approved 229:6 234:8,9 approving 50:8 254:15 approximately 193:17,18 216:15 APR 34:21,22 42:7 APR-DRG 32:2 34:9 36:17 41:10 279:19 APR-DRGs 30:5 31:20 32:11 35:10 36:2 42:5 area 17:21 50:16 51:3 106:14 177:1	areas 48:7 194:22 195:10 202:1 218:16 368:3 387:15 388:2 arena 146:8 368:14 argue 255:12 359:6 argument 56:18 132:15 arguments 141:20 288:7 Arizona 102:7 arms 371:3 array 340:7 arrest 55:6,17 arrival 317:12 322:9 391:17 arrive 140:20 293:15,16 arrives 293:8 arriving 104:2 art 382:13 article 261:8 artificially 44:14 82:4 aside 337:6 asked 22:15 30:12 34:17 48:3 51:14 67:13 73:22 128:12 188:7 197:4 200:3,6 210:17 220:15 249:14 255:14 320:6 asking 22:8 147:10 167:7 212:6,7 220:9 232:12 266:13 276:22 278:4 319:6 348:7 379:13 ASLHA 193:2,5,7		

axis 66:22	balance 301:6	355:8	believer 247:15,16	47:7 59:7 70:10
a-fib 321:12 322:1	bar 383:10	basis 37:17 254:17	benchmark 146:11	75:11 79:20 80:6
A-S-S-I-G-N	BARRETT 1:15	377:16	146:14 221:3	84:22 85:22
280:19	203:21 218:3	batch 398:2	benchmarking	107:19 117:6
a.m 1:10,15 5:2	229:20 231:15	Battelle 3:7 24:17	66:3	130:6 141:14
192:8,9 203:20	239:7 248:2 334:8	Bautista 1:17,18	benchmarks	148:4 154:1
218:2 239:6 249:8	344:20 372:22	49:21 64:9 66:10	108:15	156:18 161:9
	barriers 158:15	101:17 150:14	beneficiary 384:21	162:22 170:1
B	BARSAN 1:16	190:3 202:9	benefit 87:19	177:7 178:15,19
b 54:5 72:10,14	51:12 52:1,4	209:15,21 210:12	105:18 227:17	187:16,17 189:1
112:5 187:17	179:15 246:3,12	212:5 219:18	229:8	208:8,14 220:1
256:20 371:6	246:17 288:10	221:19 243:17	benefits 115:21	238:14 254:5,7
baby 255:1	328:15,20 376:22	285:22 289:18	Bernard 55:16	269:10 282:21
back 6:5 12:7 20:18	386:1 389:16	290:14,19 297:13	Bernheim 3:2 84:6	329:7 330:18
38:10 52:20 60:6	390:5 391:8	318:13 324:1	84:7 95:17 96:3	337:12 365:2
60:14 64:15 70:15	base 294:15	329:3 333:14	96:21 97:5,9,12	371:6 375:20
72:8 100:4 110:4	based 9:19 13:13	334:21 343:5,16	97:17,22 98:20	384:6
129:11 130:3	13:21 32:6 39:2	344:4 355:11	100:16 103:5	beyond 172:17
131:2,16 135:11	42:5 45:3 51:8	Beach 1:21	104:9,14 105:2	173:7 177:19
139:11 140:1,3	56:4 67:18,19	bear 196:10	106:20 107:2	194:2 218:9 255:1
141:8 165:3 166:9	72:3 73:8 81:2,9	beat 336:19 382:20	112:21 113:4	296:12 302:16
175:21 185:3	83:10 86:10 90:11	beating 346:16	114:6,9,13 116:8	308:13
187:6 192:5	95:14,15 96:10,15	beds 27:7	120:12,15 130:8	bias 44:7 149:17
199:20 208:7,12	111:13 112:1,2,3	beginning 89:6	133:2 134:1	262:19 293:18,19
208:17 215:6	113:15 119:19	148:20 195:15	135:10 136:19	big 44:18 74:11
220:22 221:17	120:8 123:14	208:2 284:22	142:6,13,18	143:11 203:13
226:11 228:18	134:18 138:20	314:22	143:20 144:14,17	215:11 219:11
229:5 238:6,11	176:3 186:21	begins 209:10	145:20 146:13	287:21,22 324:14
249:7 251:4	191:14 193:14	behalf 395:7	152:16 155:13	328:7,21 338:15
273:19 289:1	212:21 222:22	behavior 134:20	161:10,20 165:5	355:4 356:18
297:4 298:8	243:10 245:19	178:22 179:1,2	174:6,20 179:22	bigger 138:17
305:16 314:20,21	260:5 276:7,12	behaviors 140:22	181:9 186:11	biggest 353:22
319:5 344:17	278:16,17 282:16	141:3,4	187:2,5 188:1,11	391:8
351:3 357:4	292:19 293:13	belabor 58:7	189:5 190:7,13	bill 38:20 51:11
364:12 365:20	294:10,17 307:11	belief 173:14	291:16	109:12,16 110:2
382:21 393:10	359:10 361:17	believe 34:6 106:15	best 16:14 51:4	111:14 179:13
background 5:19	362:2 366:8 370:7	142:22 166:2	71:9 88:10 153:10	246:2 288:9
7:9,19,22 196:4,7	396:11 397:2	170:2 178:5 186:4	156:6 207:13,22	328:14 376:21
196:11 389:6	baseline 152:11	193:22 200:8	208:17 216:14	385:22 392:5
backhanded 298:1	262:11,12,14,18	201:21,22 231:11	238:14 265:14	billboards 156:13
back-burner 245:8	basic 281:2 284:6	247:18 250:9	282:6 316:14	billed 367:20
bacteremia 366:18	basically 42:9,15	301:5 306:20	360:21 377:12	billing 33:9 37:2
bacterial 293:12	195:14 202:10	307:12 310:15	392:15,15	90:12 109:5,11,18
bad 50:10 132:4	203:7 210:16	336:1,14 344:9	beta 171:19	110:7,21 111:5
148:22 157:2	249:1 266:9 271:5	354:21 368:16	Beth 1:23	112:5 115:12
322:19 337:16	276:22 282:9	383:16 384:22	better 14:21 21:6	119:20 120:9
375:6	289:22 290:15	385:7	21:13 35:22 44:15	260:8 336:3

366:22 367:8,12 370:8 binary 67:14 birds 264:22 bit 5:10 6:17,20 7:2 11:10 20:8,11 28:21 107:3 136:6 140:14 143:16 166:10 196:4,7 214:9 232:9 238:6 254:10 264:9,21 265:1 269:19 297:16,20 299:12 299:15 321:9 326:8,12 353:5,21 black 32:11,16 34:19 36:11 56:12 92:22 blame 387:7 388:1 389:21 bleed 320:12 block 314:7 blockers 171:20 blood 100:22 366:12 board 71:13 158:2 158:4 165:17 396:18 board's 184:5 bodies 225:20 body 183:14 184:8 233:2,10 241:1 244:4 bone 129:20 borders 177:19 Bott 3:4 24:16 64:13,13 310:13 310:13 bottles 366:13 bottom 253:20 bound 176:21 box 32:11,16 34:19 36:12 brain 294:13 brave 361:1 break 50:2 192:4 breath 122:4	bridge 178:20 brief 90:1 282:16 336:21 briefly 35:8 181:10 372:3 bring 63:2 102:13 107:11 108:9 115:1 159:16 185:2 231:1 237:20 277:6,9 299:4 304:3 346:3 351:3,19 355:2 363:16 364:7 388:10 bringing 84:11 89:17 103:6 264:20 broad 275:20 286:17 broader 277:8 299:1 341:5,18 354:5,7 355:1 358:22 broader-based 253:9 broadest 16:13 275:14 289:7 broadly 303:18 broken 238:7 brought 34:4 81:18 102:17 183:9 197:9 227:22 312:18 brown 214:2 bucket 189:3 budget 373:8 BUHR 1:19 308:19 build 87:4 319:9 building 88:10 built 88:13 bunch 6:16 bundled 179:20 180:3 bundles 179:20 burden 277:1,3,15 277:21 278:3 279:1,3,5 319:15	319:21 320:22 325:20 346:14 347:8 361:2 379:1 379:8 380:17 burdensome 393:13 burning 185:7 BURSTIN 2:13 20:10 69:3 77:1 157:16 217:10 251:12,15 252:11 252:14 259:11 267:14 269:1 287:10 291:10,15 302:1 303:2,15 332:3 345:4 348:15 350:9 351:15 352:21 353:20 354:20 356:3 357:11 369:16 377:11 379:4 390:10 398:8 bus 176:21 business 363:21 button 119:12 buy 338:6,10 buzzword 373:19	263:3,3 cacophony 350:14 351:22 calculate 75:3 162:15 calculated 32:14 calculating 65:19 calibration 10:3 22:14 62:19 California 3:18,22 42:20 43:2 102:7 call 31:5 43:21 150:8 200:4,7,8 200:10 218:12 233:15 235:3 249:7 271:3 310:16 312:19 330:15 378:6,19 383:2,18 384:14 388:18 391:16 396:7 397:13,14 called 11:17,18 64:15 76:16 156:11,11 193:9 389:4,8 caller 173:21 calling 358:5 calls 375:17 397:18 cancer 129:13 131:4 candidate 4:4 103:15 candidates 201:20 387:17 canned 310:16 capability 336:2 capacity 21:20 48:22 176:5,18 308:13 316:21 337:14 capture 110:10 111:5 176:5,8 190:8 289:7 338:16 342:7 385:7 captured 186:5 345:2 363:6	captures 20:11 334:17,20 capturing 74:16 365:11 car 131:5,13 card 392:6 cardiac 48:8 55:6 55:17 104:20 145:9 cardiologist 156:22 Cardiology 361:20 cardiovascular 104:18 287:12 care 1:13 9:21,22 10:1,16,18 15:7,9 18:18 23:13 29:17 37:20 44:13 47:20 52:17 54:22 55:3 55:9,12 56:3,13 57:3 59:6,7 74:17 77:22 85:21 86:21 90:14 98:15 99:4 107:12,15 108:14 108:18,19 109:8 111:15,16 112:7 116:12 117:14,16 117:18 123:3 130:16 132:16 138:2 142:8,9,20 143:7,12 145:13 148:4,12 151:16 153:2 154:15,16 158:12 166:5 168:1,5,20 170:5 177:3 179:3,11 183:16 189:16 202:1 203:17 209:2 214:21 216:12,19 231:5 232:16,20 236:16 238:15 240:19 241:4 244:13,15 248:12 253:6 254:7 256:1 259:21 260:9,13 260:14 263:16,17 275:16 302:18,20
C				
C 30:16 40:21 41:1 42:2 43:3 45:8,11 60:10,20 61:3,10 62:1 79:14 80:6 88:15 106:14,17 106:21 107:5,17 134:7,9 136:11,18 138:11,22 139:8 142:3 143:17 159:19 160:3 161:13 162:11,20 163:18 164:10,19 166:12,20 167:5 167:15 169:14 170:12 175:21 178:6 180:10,11 184:12,18 187:18				

305:15 306:6 318:16,18,22 325:6 339:11 341:16 347:22 365:4,19 368:4,5 368:9,16,21 369:1 373:11,11,15,15 380:1 384:18,21 385:13 386:2,2 390:7 391:14 career 239:21 373:5 careful 53:11,18 98:13 99:1 116:21 180:21 carefully 45:19 86:8 carotid 130:17 carried 377:2 carry 223:11 cascade 346:7 case 10:6 85:16 88:17 105:17,17 106:13 107:15 123:3 131:12 132:6,8 143:1 156:3 164:12 180:4 187:15 210:3 213:13,17 235:18 244:15 251:19 267:9,15 268:3 286:12 300:7 308:5 312:3 313:18 338:11,18 338:22 339:6,8 365:17 cases 9:1 23:9 54:14 65:15,22 222:11 314:1 352:4 case-in-point 64:17 casual 76:3 CAT 388:18 catch 192:16 291:8 catch-22 225:7 categorical 35:11 36:2	categorically 103:11 categories 16:5 27:3 199:7,12 299:18 397:12 categorize 124:20 caught 240:9 247:14 264:5 causal 155:15 cause 50:18 90:7 146:3 157:9 237:2 342:18 caused 208:8,9 caution 107:5,22 CC 103:16 CCC-SLP 2:10 CCs 103:8,18 104:14 ceiling 326:8 cell 309:5,13 center 1:22,23,24 2:2,5,6,8 3:3,6,10 3:14,15,22 47:20 84:8 132:15 152:20 387:19 centered 29:19 centers 50:2 263:17 388:17 centralized 111:17 cerebral 102:20 104:4,10 109:4,21 cerebrovascular 104:17 certain 48:10 59:6 105:2 133:16 171:12 208:6,11 239:4 317:3 387:13 certainly 15:4 16:15 17:8,20 19:6 63:8,13,16 64:2 106:16 135:4 139:14 140:5 141:3 159:11 178:12 184:14 194:2 195:3 222:5 222:8,22 226:2,6	226:12 230:16 239:8 251:22 253:8 291:4 294:1 295:12 296:2 299:2 309:6 312:19 382:10 393:13 certification 77:4 334:11 cesspool 337:1 cetera 125:10 151:19 211:18 228:1 262:16 396:1,11 chairs 199:20 challenge 137:19 220:11 255:14 377:22 challenging 12:13 134:3 166:1 chance 102:15 106:1 129:2 162:22 220:14 242:10 396:4 change 5:9 83:14 166:17 178:22 179:1 185:21 205:22 238:10,12 238:13 246:22 247:7 319:15 358:12 379:3 changed 253:21 changes 49:11 72:16 179:2 349:3 352:4 360:22 397:2 changing 168:12 207:11 375:11 characteristics 39:3,5 48:21 106:1 108:21 117:16 135:19 136:3,6 138:21 139:14 140:6,17 140:19 160:1 161:2 170:8 171:9 292:20	characterized 161:8 charge 388:15 chart 29:9 39:22 69:15 89:4,19 95:15,19,22 96:4 96:6 101:3,10 103:22 104:2 105:17 106:7 108:1,4 131:20 133:4,18 139:3 161:11 181:19 266:6 322:21 366:7 370:22 charted 110:18 charts 62:13 181:21 327:6,7,8 chart-abstracted 95:8 chart-based 167:2 chatted 394:7 check 203:2 251:4 checked 39:13 Chicago 235:5 chief 5:17 children 306:10,15 Children's 2:6 chime 252:16 choice 78:3,3 154:10 choose 266:1,2 273:1 286:22 290:10 301:8 320:18 385:19 choosing 298:12 chose 237:22 chronic 306:17 Circulation 262:21 circulatory 104:19 city 27:6 51:3 156:12,17 386:7 claim 348:3 claims 40:12 85:10 85:12,13 86:16,17 88:14 89:15 99:20 123:10,15 133:6 139:4 167:3	278:16 347:21 claims-based 379:6 clarification 121:9 200:2 201:17 234:22 243:1 383:9 clarify 54:20 80:3 166:16 167:6 180:9 190:4 215:3 290:5 347:10 classic 100:19 299:20 classifications 276:13 classified 34:3 261:1,3 262:2,4 classify 125:8 247:7 clear 19:11 54:6 68:9 76:11,21 130:13 141:13 155:20 196:20 246:4,6 255:20 293:14 295:14,15 323:20 348:6 cleared 370:1 clearer 113:18 330:18 clearly 53:14 78:19 168:6 169:10 252:4 253:10 Cleveland 1:17 3:12 Clinic 1:18 2:6 3:12 clinical 36:3 39:21 57:5 60:1 69:16 70:8 80:8 98:11 105:4 113:5 128:21 129:6 130:14 139:7 140:19 249:11 293:14 294:16 295:18 301:1 306:18 340:20 341:16 361:15 362:3 370:21 383:4
---	---	--	---	--

clinically 15:4 51:20	122:12 128:12 157:2 209:2	192:22	105:8 130:3 131:2 131:16 133:6	199:22 203:21 218:3 229:21
clinician 53:4 116:22 160:16 193:8 195:6 266:22 267:19 268:10,21 269:6 289:20,21 290:4 291:18 298:6 328:1,9 329:14 332:9 334:15,18 348:19 356:17	220:15 253:4 263:19 285:5 298:19 300:19 301:22 302:6 305:13 310:3 313:7 367:7 coalition 64:17 coalitions 47:14 code 33:9 103:7 110:21 149:22 367:8 384:20 388:16 389:4,5	colleagues 133:3 261:6 262:20 collect 74:22 75:1 165:21 263:9 277:17 370:12 379:14 collected 87:18 89:12 164:1 260:7 263:13 307:5 336:11 339:13 342:21 collecting 120:16 193:10 336:2 339:2 346:14	139:22 140:3 141:8 156:20 169:13 204:21 215:6 283:7 294:11 297:4 298:8 303:10 305:14 309:22 329:19 357:4 365:20 370:6 377:5,15 380:22 391:10 comes 18:1 27:15 102:4 129:11 241:22 335:18 371:13 391:16 397:10	250:14 258:22 259:3,12,15 287:17 298:11 325:20 326:20 334:7 340:11 348:16 355:19 360:19 361:9 392:9 393:2 395:18,20
clinicians 35:12 36:5 110:11 111:3 160:14,18 193:5 193:17 194:15 198:17 199:3 224:16 225:1 268:14 295:22 342:8 385:4	coders 366:15 coders 111:17 341:9 366:11 codes 37:2 67:19,20 90:12 103:10,14 104:15 109:12,14 110:3,7 111:14 112:2,4 180:4 299:22 307:12 366:22 389:8	collects 103:8 334:22 College 2:2 261:19 361:20 colored 384:16 column 114:6,10 114:11,13 columns 318:8 com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	377:5,15 380:22 391:10 comfort 44:13 77:21 260:12 comfortable 29:3 62:1 72:4 83:13 151:10 253:18 359:4 comfortably 254:12 coming 12:7 23:5 33:2,13 37:14 38:1 78:3 89:8 100:8 105:16 115:3 116:19 117:1 134:15 138:7 226:11 227:9 284:20 291:12 340:2 392:18 comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	comments 26:4 27:9 28:8 35:4 41:9 71:15 76:6 80:19 82:18 83:16 91:18 92:8 93:16 94:12 109:1 114:22 118:12 119:8 120:1,11 121:4,19 123:22 124:14 127:4,15 144:20 152:17 182:10 188:14 190:2,21 191:6,21 201:14 218:19 228:6 229:3 231:14 236:4,19 243:15 248:7,19 258:18,20 259:10 263:22 309:16 319:2 327:19 355:19 360:6 361:6 362:10 375:5 384:12 394:18,20 396:4,6 396:8
clinician's 258:5 359:11	coding 109:6 306:13 341:12 370:8 coefficient 43:22 97:19 coefficients 31:9 102:16 114:5,18 300:12 312:10	com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	comfort 44:13 77:21 260:12 comfortable 29:3 62:1 72:4 83:13 151:10 253:18 359:4 comfortably 254:12 coming 12:7 23:5 33:2,13 37:14 38:1 78:3 89:8 100:8 105:16 115:3 116:19 117:1 134:15 138:7 226:11 227:9 284:20 291:12 340:2 392:18 comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	Commission 3:13 3:20 75:14 315:9 315:20 316:19 325:6,17 328:2 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 347:5 353:17 354:2 358:10 360:20 362:15
clinician-level 267:12 268:4 334:19 342:1,2 345:10 360:11 362:17	cohort 78:8 308:3 cohorts 46:21 292:18 293:13 308:7 collaboration 142:8 158:20 159:5 collapse 215:4 316:11 collaterals 337:6 colleague 168:9	columns 318:8 com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	Commission 3:13 3:20 75:14 315:9 315:20 316:19 325:6,17 328:2 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 347:5 353:17 354:2 358:10 360:20 362:15
clock 352:12 389:1 close 7:16 41:1 74:9 82:12 88:7 176:20 271:22 315:22 327:19 380:8 381:6	coefficient 43:22 97:19 coefficients 31:9 102:16 114:5,18 300:12 312:10	columns 318:8 com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	Commission 3:13 3:20 75:14 315:9 315:20 316:19 325:6,17 328:2 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 347:5 353:17 354:2 358:10 360:20 362:15
closed 157:4 closely 96:12 closer 74:13 closes 396:2 closing 397:14 clustered 11:14 13:19 clustering 14:13 30:1 85:17 91:11	cohort 78:8 308:3 cohorts 46:21 292:18 293:13 308:7 collaboration 142:8 158:20 159:5 collapse 215:4 316:11 collaterals 337:6 colleague 168:9	columns 318:8 com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	Commission 3:13 3:20 75:14 315:9 315:20 316:19 325:6,17 328:2 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 347:5 353:17 354:2 358:10 360:20 362:15
CMS 12:16 13:1,3 13:12 14:9 21:4 73:1,10 75:19 84:11,15 99:22 115:14,16 118:6	cohort 78:8 308:3 cohorts 46:21 292:18 293:13 308:7 collaboration 142:8 158:20 159:5 collapse 215:4 316:11 collaterals 337:6 colleague 168:9	columns 318:8 com 280:19 coma 39:5 60:2 98:16 99:19 102:20 109:4 comas 109:22 comatose 80:11 combination 14:1 combine 270:16 321:14 325:21 351:13 combined 262:16 270:18,22 291:20 292:5 293:11,12 315:15 326:5 329:20 340:9 354:13 359:19	comment 4:18,22 18:7,11 24:6 34:6 34:13 36:13 41:8 47:2 53:8 57:14 60:7 73:13,18 76:9 94:5 98:18 106:21 109:3 120:12 139:12 156:9 182:11 183:6 186:20 187:8 192:13,13	Commission 3:13 3:20 75:14 315:9 315:20 316:19 325:6,17 328:2 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 347:5 353:17 354:2 358:10 360:20 362:15

commissioned 12:22	238:16 372:12	complementary 344:18 345:22	compute 14:4 334:14 336:9	conference 1:9 375:17
Commission's 347:1	comparable 61:11 88:15 309:1 379:15	complete 34:22 109:6	concede 80:22 81:12 82:6	confidence 87:12 105:7 167:9 188:9
committee 1:4,9 4:23 13:1 14:20 16:19 17:22 18:1 50:6 60:16 61:19 63:11 64:3 107:5 130:13 157:7 165:15 200:9 237:21 263:20 280:13 281:18 287:13 302:11 303:8 314:18 315:14 325:13 351:4,11 357:16 396:18 397:2,19	comparative 40:16 41:5	completely 78:15 90:11 129:10 137:17 140:8 161:1 242:1 267:22 273:5,7,10 296:16 299:9 301:12 304:1 319:17 343:6 351:16 379:6 392:4	conceding 81:22 concept 55:2 89:5 168:14 174:20 350:10	confident 89:16 173:4
committees 15:2 17:18 105:11 303:5 309:8 380:4	compare 16:17 66:4 89:1 95:9 199:18 221:2 265:13 266:1 270:11 271:4,14 273:6 297:14 300:11 315:8,9 329:6 338:1 355:15 371:14	completion 313:5	concepts 271:2 286:17 287:14 351:19	confirm 31:8 32:1 39:1 111:3 117:12 230:3
common 21:9 50:17 351:9	compared 39:19 67:15 92:22 93:2 108:16 115:22 126:17 139:6 161:6 263:13 277:3 297:17,20 348:21 393:22	complex 7:12 8:13 83:20 155:16 166:4 170:10 181:16 297:8 371:22	conceptual 270:12 286:8	confirming 367:5
commonly 173:11 195:1	comparing 29:8 88:11 97:3 261:10 261:20 329:5 356:13	complexities 382:7	conceptually 86:20 177:22 266:13 267:3 347:18	confronted 366:4
Commonwealth 71:9	comparison 12:12 14:3 22:2 163:11 299:15	complexity 158:10	concern 36:21 41:9 52:15 115:13 120:18,19 155:5 161:21 163:17 167:15 180:9 227:18 331:8,9 343:11 383:14	confused 111:13 145:9 156:21 232:5 256:5 296:7 347:11
communication 4:9 4:10,11,12,13,14 4:15,17 138:3 142:8 144:10 164:7 200:13 211:4 212:20 213:3 235:15 239:10 256:9 373:22 384:6	comparisons 8:11 199:9	compliance 323:16 343:22 371:18	concerned 165:1 186:20 204:2 226:21 254:11 302:16 383:2	confuses 100:17,20
community 89:8 153:12 159:5,8 176:22 179:4 294:3 344:17 367:10 387:22	compassion 51:5 63:9	compliant 139:22 141:7	concerning 159:20	confusing 96:16 214:9
community-based 149:18 158:16	competing 4:20 7:3 16:11,14 146:20 264:4 265:2,5,11 265:22 266:8 267:5 269:16 270:4,9 271:3 273:21 274:4 279:4 282:10 285:7,9 286:3,6 287:18 315:13 350:11 353:18 356:15 376:2 380:16	complicated 6:21 50:16 140:4 242:10 297:9 306:14 372:7	concerns 52:21 71:19 72:1 149:4 159:19 160:11 350:20	congenital 104:20
comorbid 100:11	compassion 51:5 63:9	complication 99:9	concerns 52:21 71:19 72:1 149:4 159:19 160:11 350:20	congestive 151:17
comorbidities 40:1 208:9 262:15	complaint 110:11	complications 39:9 92:19 99:3,17 107:15 142:14,20 168:17 170:20	concerned 165:1 186:20 204:2 226:21 254:11 302:16 383:2	Connecticut 97:4 384:22 388:14,19
company 208:21		component 37:6 91:7,12	concluding 182:15	connection 177:7
		components 34:9 144:7	conclusion 121:12 164:19 191:14	consciousness 102:21
		composed 53:14	conclusions 72:3 268:22	consensus 11:13 75:22 239:12 362:3 396:17
		composite 294:7 318:17 319:10 325:14	condition 99:22 100:1 103:7 158:10 330:14	consent 55:20
		Comprehension 4:14	conditions 25:2 57:5 98:9 100:11 102:18 106:3 293:5 295:12 301:1 397:5	consequence 36:11 228:1
		comprehensive 63:14 160:17	condition-specific 189:19	consequences 66:17 211:10,17 380:2
				consider 16:19 17:3 86:22 124:17 125:8 164:8 245:7 265:4 267:3,4 273:11 276:1 281:17,21 285:7 285:11 294:2,6 315:12 358:14,21 360:21 361:14 376:1

295:6 301:17	333:10 381:4	32:5 43:17 52:3	374:4	143:9 144:12,15
308:4 330:12	continued 225:8	52:10,11 53:4	covariates 30:2	144:19 146:17
349:5	continuing 57:10	98:1 121:10 186:6	67:18,19 68:2,8	147:6,12,15 149:6
considerations	317:22 390:20	190:14 202:3,4	91:3 170:8	150:12 151:7,22
12:7	contract 84:11	218:14 283:2	cover 81:20	156:8 157:14
considered 6:12	contrary 243:14	285:15 305:12,19	covered 311:5	159:13 161:3,15
19:2 86:3 94:10	313:1	308:1 310:18,21	Co-Chair 1:13,14	162:5,9 163:15
103:2,7,14 160:17	contribute 57:2	321:9 354:6,8	6:4,15 22:21 24:4	165:4 166:14
188:10 247:1	contributing 104:7	correctly 88:19	25:12 26:3,7,16	167:20 169:5,11
275:9 276:9	181:17	160:6 267:13	27:8,12 28:7,11	173:16 174:2,10
281:22 314:9	control 141:11,18	323:8	30:22 33:5 35:15	174:18 175:17
322:10 328:12	147:20 153:8	correlated 40:5	35:21 36:14 37:8	177:14 178:10
348:22 364:3	154:4,7,18 155:3	42:10 95:12,13	37:17 38:9,19,21	179:13,19 180:7
considering 63:11	172:17,19 173:7	96:13 161:13	43:9,12 44:10	182:9,18 183:5
200:12 281:17	175:5 178:14	correlating 96:19	45:22 49:1,20	185:6,12 186:19
286:6	282:18 385:17	96:21	50:12 51:11 52:5	187:4,20 188:4,13
considers 85:20	controlled 223:22	correlation 11:14	54:10 56:16 57:12	189:22 190:11,16
consist 195:13	controversial	13:19 42:6 43:4,4	57:15 58:5 60:13	190:20 191:5,9,20
consistency 197:14	365:14	43:7,22 89:20	60:21 61:20 62:21	192:3,10 199:21
241:1	convened 128:12	95:19 97:8,19	64:6 65:18 66:8	200:11 201:13
consistent 62:14	conversation 23:18	106:5,10 213:22	66:19 67:3,6 69:2	202:7,20 203:4,20
236:13 303:22	28:13 69:8 94:19	cost 35:2 378:21	69:19 70:12,20	204:8 206:18
310:12 330:19	128:3 235:9 333:6	380:14	71:14 72:5,18	207:2,18 209:14
376:14	conversations	costs 372:10 379:14	73:11,15 75:16	210:9 212:3,14
consistently 87:18	94:21 292:1	Counsel 2:14	77:12 78:22 79:11	213:19 214:17
165:8 180:5	converted 83:7	count 122:18	80:18 81:15 82:7	215:5 217:5,9
Consortium 66:6	convinced 223:7,14	counted 372:9	82:11,17,21 83:8	218:2,19 219:17
71:11 261:18	321:8	counterpoint 56:18	83:15,19,22 91:18	220:7 221:17
construed 41:13	convincing 231:4	66:11,11	92:1,6,12 93:15	222:20 223:2
consult 209:17	250:11 333:9	countries 193:20	93:21 94:11,16	224:9 225:11
consultation 86:6	cool 268:19	country 18:19 27:4	95:5,21 96:18	226:18 228:4,11
368:21	COONEY 1:20	126:1 391:22	97:2,7,10,14,21	229:2,4 230:9
consulted 86:7	57:13 79:1 112:13	392:3	98:2 100:9 101:12	231:2,13,17
consumer 79:2,10	113:3 248:21	County/Spectrum	101:21 102:8	233:12 234:3,7,13
135:4	268:18 290:20	1:21	106:22 108:6,22	234:17 236:3,9,18
contain 364:20	303:20 344:14	couple 5:11 10:10	111:10 112:6,12	237:16 239:6
CONTENTS 4:1	368:15	31:3 32:9 64:15	113:10 114:1,11	241:13,16 242:21
context 9:8 87:1	coordinate 166:5	84:3,19,22 131:9	116:6 118:11,17	244:17,21 245:2
141:1 158:6	coordination	180:3 194:7	119:4,16 120:10	245:11 246:2,14
193:16 214:21	144:11 168:17	217:19 248:7	120:13,20 121:2,7	246:19 247:8
216:11 218:1	232:20	287:20 323:13	121:17 122:2	248:20 249:5,19
contiguous 85:21	copy 35:1	372:18 381:14	123:16,21 124:4	250:13 251:1,14
continually 171:8	core 318:16	382:1 395:15	124:10 125:11,17	252:9,12,15 255:8
continue 61:2	Cornell 2:1	course 22:5 44:2	127:3,9,14,21	256:2 257:3
75:14 221:18	corollary 50:14	66:12,13 122:22	129:3 134:5 136:9	258:14 259:1,9
245:9 248:5	129:17	169:13 220:1,6	139:16 140:10	263:21 264:7,15
252:19 290:12	correct 31:10,11,13	306:10,15 309:3	141:19 142:11,17	266:18 268:8

279:22 280:5,9	critical 35:9 88:2	40:11,12,19 42:20	316:13 319:16,18	109:18 112:17
281:10,13 283:21	253:11,12 384:18	43:2 45:20 47:14	319:18,22 320:7	115:5 150:8 172:1
287:16 288:22	388:12	47:16 51:8 52:12	320:20 322:18,19	174:2 229:7
292:12 299:8	critically 255:18	52:14 57:20 62:10	323:6 325:2,10,20	267:22 315:7,11
307:8,20 315:18	CRNP 2:3	68:5,6,7,16,21	326:22 327:14	316:6,8 317:9,19
317:16 321:21	cross 189:12	70:4 72:22 73:6	329:19 334:3,5,17	321:12 348:22
325:19 330:10	crossing 105:8	75:1,4 79:3 80:8	334:20,22 335:1,5	349:6,19 366:6
332:22 339:16	crosstalk 207:19	82:14,16 85:10,14	335:12,14 336:2,3	397:16
348:18 350:7	cross-links 302:4	86:16 87:16 88:6	336:11,14 338:17	days 25:22 90:8
354:15 360:18	cross-reference	88:8,13 89:4,13	339:1,12,22 340:3	123:9 172:16
368:1 372:2 375:4	348:2	90:12,18 93:7	340:8 342:20	314:8 327:7,9
384:13 387:1	crowding 390:16	94:9 95:8 96:8	343:20 347:14	DDS 3:1
388:10 389:19	crutch 136:11,18	101:2,10 102:9	348:1 352:5 361:2	de 2:10 96:4 144:21
391:13 398:6	crux 94:20 331:21	112:9 114:17	366:6,22 367:1,1	146:5,22 147:9,14
co-chairs 1:11 6:3	CT 6:13 365:13	115:13 119:19	367:12,13,19	188:15 207:21
CPE 1:21	culturally 392:10	120:2,4,9,16	369:11 370:7	220:9 228:17
Cramer 248:10	cultures 366:13	123:10,15 126:4	378:21 379:8,14	229:16 231:20
cranioplasty	current 69:10	132:20 133:1	381:19 391:4,10	238:5,20 239:14
130:18	289:12 329:21	139:3,4 147:17	391:10,16,18,20	239:20 252:17
craniotomy 41:18	currently 8:9,22	151:2 160:2	391:22	258:1 343:11
41:19	16:16 20:2 23:2	161:19 163:22	database 39:20	344:2 392:7
crash 131:13	24:21 144:6	164:22 171:7	204:4,20 218:10	Deaconess 1:23
crashes 131:6	145:16 178:18	176:9 181:1,4,19	data-based 96:10	dead 246:9 346:16
crazy 129:13	193:12,15 199:18	181:20,22 182:17	date 173:22 174:5	382:21
create 96:6 99:6	282:1 301:14	183:22 191:4	380:5 381:1	deal 30:1 69:9
271:9 371:22	310:18 368:22	193:8,10,14	Dave 5:12 22:20	350:5
376:7	curtain 280:2	194:15 197:19,21	343:6 350:20	dealt 201:3
creating 312:6	curve 106:15	198:1,2 200:18	381:7,8	death 23:9 25:21
325:14		203:18 206:13	Dave's 348:16	49:19 50:15,17,19
credit 170:19	D	212:21 213:8,9,9	David 1:10,10,13	51:4 56:20 77:17
credited 235:4	Dan 77:13 147:15	215:10 216:3	1:14,23 5:11	78:9,17 79:6 90:7
crisp 380:3,5	149:10 152:16	217:1 219:4,18,20	38:19 57:15 58:10	92:21 100:13
criteria 6:8 8:6,21	159:6 175:17	222:4,7,9,12	102:17 201:14	122:22 152:5,9
8:22 9:9 17:17	177:14 207:2,21	227:11 233:18	234:11 261:5	292:7 296:11
22:11 25:16	295:8 296:5	235:18 236:1	287:15 292:9	305:15
100:15 101:14	336:17 366:1	242:5 257:15	299:7 330:9,21	deaths 26:1 50:19
118:2,3 129:7	danger 309:3	260:7,8,8,8,9	336:22 360:17	59:9 79:8 92:16
156:16 183:8	Daniel 2:2 50:12	261:13,16 263:1	364:8 367:22	debate 349:5
184:16 185:3,5	300:5	263:10,12 267:21	375:3 383:21	382:18
206:3 225:14	Daniel's 56:18	268:6 269:9,10	392:9	debating 247:12
229:22 260:5	Dan's 152:2 178:12	277:16,17 278:13	Dauids 398:9	decide 140:1 186:9
265:6 270:6	dashboard 63:15	278:19 279:1	David's 159:18	221:10 233:7
271:15,17 371:2	data 8:12 10:6	284:12 296:16	173:20	250:17 274:7
374:22 379:19	15:14 19:17 20:22	298:21 300:7	Davis 3:18,22	278:1 279:3
criterion 9:11	21:5,9,21 22:1,3,4	302:4 305:13	24:12,19 33:18	289:20 331:12,21
10:11 29:6 237:8	23:5,15 25:7,9,9	306:8 307:3,5,10	65:6	351:11 386:3
275:4	25:10 29:9 34:1	310:1 311:18,21	day 4:2 7:4,7 39:15	decided 273:22

282:9,11,15	degree 111:4	198:20 250:16	51:13 60:20 61:2	diagnoses 32:6
287:13 307:22	234:18	309:20 379:5	83:4,11 84:3 94:6	131:5 133:16,16
331:14 341:17	dehydration	depends 147:19	94:21 95:6 176:7	146:8 188:21
decile 62:13,18	157:11	depth 349:4	192:12,19 216:8	diagnosis 23:10,17
deciles 66:21	delayed 387:18	described 41:15	218:6 226:21	29:8 67:19,20
decision 53:5 72:11	deliberations	describing 41:5	230:2 232:14	69:16 90:9 130:22
72:12 329:16	237:13	description 233:2	233:4,9,22 235:19	145:2,5,10,16
decisions 55:7	delirium 397:9	284:7 290:21	236:13,22 237:21	146:11,18 147:5
74:11 116:13,15	deliver 386:11	design 142:10	243:18 245:9	276:13 307:11
249:18 395:22	delivered 253:15	designed 25:6,8	248:22 249:13	321:18 330:16
decision-making	347:22 365:7	47:12 86:19 117:7	251:4,10 283:18	337:10,13,22
78:14 260:12	delivering 176:12	142:1,7 146:14	289:14 315:19	341:9,12
decrease 319:21	delivery 389:2	153:7 190:8	319:3 325:4	diagnosis-related
deep 5:22 75:22	delta 369:19	detail 8:7 69:9 92:7	363:17 381:18	30:6
122:3 161:22	delve 5:22 18:6	96:2 183:14 197:5	383:6	diagnostic 62:12
296:11	186:8 283:10	265:1 283:14	developers 13:7	293:18,19 294:20
deeper 60:15,15	365:13	335:7 355:14	15:16 17:9,19	308:10
deeply 169:15	demand 50:6	detailed 39:21	21:22 31:5,8 32:1	diastolic 293:10
171:14 173:8	337:12	40:12 196:19	32:19 38:22 62:2	dictate 8:8 110:13
defects 104:20,20	demanding 243:2	335:4 353:8,10	62:7 66:21 71:21	326:7
defend 255:5	dementia 179:18	details 32:13	92:15 98:5 125:20	dictated 12:8
defending 349:13	397:7,9	191:15 229:18	128:3,10 134:6	die 44:13 46:10
defer 291:14	demographic	252:11 278:18	140:11 159:21	58:21 113:16
deficiencies 172:15	140:20	280:1 359:12	162:7 175:22	368:6
deficit 204:17,19	demographics	364:14 365:1	180:10 183:13	Diedra 3:12 340:10
205:2 213:5,7,16	262:15	deterioration 52:17	185:19 196:8,15	347:10 361:8
213:17 215:1,11	demonstrate 16:4	54:17 124:19	196:15 258:20,21	differ 34:18 188:19
228:1	22:13 231:22	125:2,4	271:8,12 274:17	difference 29:18
deficits 212:18,20	249:2 302:7 368:2	determine 18:18	289:15 303:19	43:18 44:18 67:1
defies 169:16	demonstrated 10:2	89:13 143:18	304:15,21 313:10	93:6,9 135:17
define 33:7 79:7	43:2,20 240:4	220:12 238:14	335:13,19 349:12	150:2 164:16
265:9,11 293:13	241:2 262:21	253:15 257:16	351:1 352:20	180:13,14 182:14
295:16,16,17	demonstration	271:17	357:3,15 364:4	205:20 235:11
defined 30:10 90:7	199:13	determined 254:1	379:13 380:19	247:11,17 278:21
126:8 292:19	denominator 14:4	374:5	383:16 384:2	278:22 287:22
defining 205:22	29:7 47:22 90:13	determining 89:2	396:3 397:13	295:3 306:6,7
definitely 241:19	90:16 201:6,17	135:9 238:22	developing 194:14	310:4 311:13
348:10 352:15	235:13 284:8	develop 96:4	292:2 311:15	328:16,21 329:2
381:6	330:8 374:21	178:19 248:10	341:1	333:22 346:15
definition 18:13,20	denominators	253:2 311:16	development 30:17	354:19 355:5,8
196:21 232:11	266:9	312:8 368:19	193:3 291:19	360:13,15 385:1,8
274:19 290:10	department 5:17	developed 99:4	377:21 394:14	391:6 393:12
326:2 338:18,19	33:11,20 37:15	122:9 193:4 194:9	devoted 7:7	differences 10:18
360:14,22	65:13 293:16	302:3 390:21	devoting 384:4	13:17 14:8 20:16
definitions 17:5	386:9	393:14	DHS 2:8	45:8 116:16 178:8
287:18 313:11	dependent 230:1	developer 21:16	diagnosed 101:19	198:22 265:21
319:18 362:18	depending 195:9	23:20,21 28:16	129:12	266:14 269:18

273:12 274:6	353:6,9,12 359:9	disagree 137:3	80:16 143:6	disorder 210:5
278:14 287:5,7,19	359:13,17 362:20	154:11 155:7	discrimination	235:22
305:4 313:16	366:6,10,16 367:9	disagreeing 332:15	10:2 22:13 89:18	disorders 104:7
318:2 328:5,7	372:5,6 378:12	disagrees 312:17	135:6	217:4 239:10
329:17 330:2	382:16 383:7,20	disappointing	discriminative	disorder-specific
362:18	386:11 389:8	45:21	106:19 159:22	195:17
different 6:17 8:2	397:4	disavowed 144:15	160:22	disorganized 392:4
8:11,15,22 9:1	differentiate	discharge 23:15	discuss 230:16	disparities 9:21
12:5 13:15 14:16	131:14 189:3	32:4 44:12 117:12	313:4 340:21	10:16,22 11:2,5
16:2,17 21:11	237:2	117:13 130:22	396:8	15:11 18:14,16
31:3 36:4 51:2,16	differentiates 38:2	141:13,14 142:9	discussed 17:10	19:7,12 20:5,9
58:11 59:20 61:15	differentiating	145:5 146:6 150:4	130:15 218:5	93:7 126:6,11,13
66:1 69:15 87:8	236:20	153:1 169:21	289:15 313:16	201:2 275:16
103:22 105:22	differentiation	171:4 173:22	353:15	373:14 392:2
108:15 112:1	87:6	174:5,9,17 175:7	discussing 49:4	disparity 19:1
113:21 115:21	differently 14:22	175:15 177:6	55:7 73:20 325:7	20:12
122:5 137:5,10,17	309:19 357:18	182:1 196:2	328:4 370:19	disparity-sensitive
143:22 145:7,17	difficult 14:19	232:19 315:4,5,6	discussion 4:19	20:4
146:8,11 150:17	17:21 31:17 65:9	315:10 316:7,8	17:9 27:17 42:1	displayed 9:6
152:6,9 154:13,13	67:1 78:14 114:20	317:12,21 320:18	46:5 55:10 89:22	disposition 23:15
156:16 180:3	170:7 173:5	321:7,11,15	91:13 121:13	disproportionate
188:21,21 215:17	180:17 221:16	322:11 323:12	141:2 146:20	47:9
227:2 237:9	247:6 252:21	327:14 328:2	152:13 158:2,3,3	disproportionately
238:13,16 240:4	271:10 363:19	338:19,20 344:18	181:14 185:18	132:17
240:19 247:3	386:16,19 389:14	360:2,12 370:15	191:17 198:12	disservice 260:22
256:6 257:22	389:15,18 391:12	discharged 44:5	226:2 232:18	distance 163:19
266:20,21 267:8	392:19	90:18 115:2,8	233:14 240:15	171:3 176:2
267:22 270:15	difficulty 37:4	123:8 177:8 306:5	252:7,21 279:8	distinct 339:21
271:11,12 273:2	380:17	320:9,12 322:17	284:22 287:1	distinction 257:8
277:18 278:8,9,13	dig 183:21 349:17	323:3 333:21	292:15 294:22	257:18 338:15,21
278:18 282:10	digit 31:21	352:22 360:1	306:20 315:17	339:3 354:1 356:5
286:1,4 288:20,21	ding 33:3 151:5	discharges 23:8	324:13 332:15	357:7
289:2 293:5,5	dinging 75:8	261:14	340:12 345:5	distinguish 34:2
296:1,13,16,16,20	direct 125:5	discharging 313:22	351:1 352:8,14	distribution 198:15
297:21 298:19	directed 229:21	discipline 209:5	358:16 360:10	diversion 390:17
299:20 300:8	direction 58:1 64:8	349:22	361:15 364:2	divide 162:16
304:2 306:18	64:12 149:1,2	disciplines 232:2	365:3,21 375:2	299:17 312:5
309:7,18 311:18	184:5 248:5	Discipline-specific	376:8 394:11	divided 118:20
313:12 314:2,13	300:14,16 310:6,7	248:13	discussions 40:8	361:5
314:13 317:15	director 2:15,17	discover 70:10	185:4 215:3	division 299:21,22
325:21 328:13	5:15	discovered 69:22	380:22	dizzying 349:11
329:4,8,19 332:2	disabilities 373:16	70:1,5	disease 259:22	DNI 52:7 53:6
332:5,10,11	373:17 374:6	discoveries 372:16	301:3 337:4,7	DNR 52:7 53:6,11
335:12 339:1	disability 103:19	discovering 148:21	373:18	54:14 55:4
342:14 344:12,22	208:6	discovery 178:1,4	diseases 306:17	DNR/DNI 54:21
347:20,21 349:22	disaggregated 61:4	discrepancy 41:4	disincentivize	55:5,11 56:4,11
350:14,17,18	79:15,21,22 80:4	discriminating	48:13	doable 251:16

doc 246:15 388:11 391:2	33:17,21 34:6,12 34:12,14 35:6,19 36:1 39:7 40:6 43:11,17 46:18 47:11 51:19 52:3 52:11 53:7 54:3 54:13 59:10,16 62:14 63:2,4,6,7 64:9,13 65:4 66:2 69:3 72:18,21 73:22 76:8,10 77:1 80:3 84:6 95:17 96:3,21 97:5,9,12,17,22 98:20 100:16 103:5 104:9,14 105:2 106:20 107:2 108:8 112:21 113:4,12 114:6,9,13 116:8 117:11 120:12,15 124:17 125:7 130:8 133:2 134:1 135:10 136:19 138:16 140:12 142:6,13,18 143:20 144:14,17 145:20 146:13 152:16 155:13 157:16 160:10 161:10,20 162:10 165:5 166:16 168:8 169:3,6,12 174:6,20 179:22 181:9 182:19 183:7 186:11 187:2,5 188:1,11 189:5 190:7,13 192:15,20,22 202:4,6 204:9 205:13 206:2,15 209:20 210:1,21 212:10 213:4 214:16,19 216:4 216:10 217:6,10 218:21 222:3,21 225:6,12 227:20	230:11 232:12 236:22 237:19 238:18,21 240:13 241:15 243:22 244:20 245:1,4 246:20 251:10,12 251:15 252:11,14 258:22 259:11 264:5 267:14 269:1 273:14 274:14 276:14 280:12 283:3 286:15 287:10 289:5 291:10,15 291:16 292:10,10 292:14 295:10 296:21 298:10 302:1 303:2,13,15 304:5 305:7,7,10 307:16 308:1 309:2 310:13 312:16 314:16 319:20 329:9 332:3 334:12 335:3 336:5 345:4 348:15 350:9 351:15 352:17,21 353:1,20 354:20 356:3 357:2,11 369:16 370:5,11 376:11 377:11 379:4 380:13 390:10 393:19 398:8 draft 395:14 396:9 drastic 349:3 draw 57:10 296:1 DRG 110:9,20 111:5 DRGs 42:8 drill 35:12 36:5 65:16 218:17 220:22 344:3 391:5 drive 51:6 178:1 drivers 380:15 drives 350:15	driving 64:12,20 78:9 138:1 178:3 219:16 225:4 240:18 243:5 245:15,18 388:19 drop 61:10 138:9 dropped 103:3 dropping 172:10 drugs 328:10 Drye 3:5 84:17 113:12,12 138:16 140:12 166:16 168:8 182:19 Dr.PH 1:22 dual 126:15,18 due 37:2 60:8 153:17 161:1 163:20 164:20 180:15 182:16 206:21 258:17 278:20 323:18 326:22 Duke 1:19 dumb 296:8 dumped 156:19 DVT 267:19 358:12 DVTs 357:8,9 358:6 dying 368:10 dysfunction 30:11 213:1 dysphagia 248:16 D.C 1:10	319:4 335:16 353:21 easily 56:15 107:19 333:5 361:4 easy 142:22 155:17 168:21 169:16 313:5 echo 383:13 Echoing 383:22 economics 382:3 ED 33:2,13,15,22 86:9,13 117:2 246:14 edema 102:20 104:5,10 109:4 110:16,17 140:1 edemas 109:21 education 6:14 50:5 66:14 144:9 144:13 177:4 effect 14:10 59:11 76:3 102:21 136:16 143:11 256:19 300:14,17 310:6 370:12 effective 183:2 347:6 effectively 34:9 308:6 effectiveness 158:11 208:2 efficient 240:20 effort 258:17 378:9 efforts 153:12 158:19 EHRs 269:11 EHR-based 277:4 277:7 eight 82:10 121:1 194:21,22 195:2,4 228:8 236:7 eighteen 94:15 119:14 121:22 250:21 EISENSTOCK 1:21 241:18 either 23:10 25:18
E				
			earlier 58:10 60:7 73:19 100:4 118:1 135:11 188:7 189:6 230:22 231:3 283:18 293:21 313:16 340:16 341:6 343:6 350:22 356:16 359:8 393:20,22 early 317:10 easier 130:9 313:9	

26:2,22 31:18 42:16 46:6 52:9 64:8 174:19 270:13 273:2 304:9 312:2 315:12 322:22 323:18 325:22 326:4 380:1 EKGs 390:8 elaborate 20:7 electronic 82:15 120:7 276:7 335:15 element 34:1 52:12 52:14 197:19,21 198:1,2 319:18 382:13 elements 9:12 68:6 108:18 120:2,6 268:7 300:8 319:18 335:2 336:15 elevation 293:3,4 eleven 190:18 191:7 eligible 123:1 126:15,18 202:2 216:15,16 224:17 224:19 eliminate 172:20 303:4 eliminated 364:10 Elizabeth 3:5 84:17 113:12 169:3 187:5 291:11 eloquently 176:7 email 280:10 281:6 397:21 embarrassingly 171:15 embedded 98:21 100:3 103:18 104:10 embrace 392:11 emergency 33:11 33:20 37:14,16 293:16 388:4	390:14 emerging 11:12 378:1 Emory 49:16 emphasize 269:15 empirical 169:16 empirically 41:6,7 employed 111:21 EMS 389:6 391:15 392:3 EMT 391:2 EMTALA 32:21 33:4,7 34:3 37:1 37:10 38:2,5,6 46:2 en 49:19 encompassed 140:8 encourage 35:3,14 36:9 130:2,4 257:20 258:15 endarterectomy 130:17 ended 175:9 endorse 16:12 58:4 74:19 227:13 257:12 258:19 268:17 290:15 332:19 333:2 endorsed 7:22 23:2 24:22 63:12 74:21 158:7 233:17 245:20 248:17 249:16 256:11,12 260:5 265:7 270:10 282:1 297:19 342:6 374:12 381:17 endorsement 1:3 9:3 49:10 63:20 75:18 76:18 77:1 82:22 121:3,16 181:7 191:10 193:21 194:11 218:9 225:8 226:9 226:11 227:13 243:2 260:20 262:8 282:19	283:8 290:13 297:5 329:12 342:17 351:18 396:16 endorses 8:17 endorsing 57:11 75:12 297:18 ends 392:17 enforcing 257:13 engagement 177:18 engaging 382:9,17 engines 296:13 England 261:7 enhance 159:4 enlightening 370:6 enormous 153:15 367:12 395:11 enrolled 90:20 113:17 enter 47:1 enterprise 382:15 entire 59:2 172:16 282:4 319:1 entirely 19:11 163:18,20 306:18 317:3 323:20 entirety 180:13 entities 47:15 entity 295:21 envelope 184:3 environment 147:1 155:19 156:6 170:22 171:13 329:21 environmental 390:15 epidemiologist 84:17 epilepsy 397:9 episode 148:12 195:16 episodes 193:13 216:12,19 equal 205:11 equally 47:6 48:15 106:11 equals 89:18	equations 14:13 equivalent 363:1 ER 38:1 109:8 371:8 388:11 erase 142:15 error 70:9 335:9 errors 70:5 especially 297:7 363:22 369:14 391:14 essence 184:5 essential 384:9 essentially 40:5 42:3,14 96:5 97:6 103:6 107:20 134:11 274:6 308:15 331:16 333:15,18 339:22 established 29:7 344:17 establishing 177:7 establishment 28:19 estimate 114:8,15 114:15 163:3 216:14 312:10 estimated 293:21 estimates 11:16 28:1 114:4 294:4 309:5 estimating 14:13 395:17 396:13 et 125:9 151:18 211:18 228:1 262:15 396:1,11 ethicists 55:16 ethnicity 10:19 20:13 92:17 etiological 321:10 321:17 evacuation 41:18 evaluate 15:2 117:8 137:11 152:22 210:14,17 236:2 265:17 evaluated 149:21 157:22 363:5,8,10	374:12 382:5 evaluates 85:6 146:1 evaluating 140:8 140:15 165:14 262:16 268:13,15 310:2 331:20 evaluation 3:4,6,11 3:14,16 84:9 93:13 126:22 251:7 256:15 266:21 270:5 271:15 363:12 evaluations 86:11 264:4 events 54:15 170:17 eventually 179:7 everybody 46:12 70:15 77:17 78:16 102:15 119:12 122:3 221:22 257:6 315:1 344:21 366:14 388:13 389:10 394:3 398:8 Everyone's 253:18 Everything's 135:18 evidence 19:18 26:9 27:20 28:14 29:2,3 50:6 64:7 64:11 70:19 71:3 71:20 92:2,13,15 95:3,4 124:13,14 125:12 142:5 144:3 160:7 165:3 168:4 180:12 181:5 182:13 183:14 184:9 186:13 197:11,13 202:10 204:12 205:8 207:5 223:6 224:7 225:18,21 227:5,12 228:10 228:14,14,15,18 228:21 229:3,13
---	---	---	--	---

230:7,10 231:5,9 231:12,18,22 233:2,10 234:4 236:8,10 237:2,8 237:14 238:2 239:1,16 240:2,5 241:2 242:19 243:1,4,6,8,11,19 243:21 244:4 247:10,19 249:3 249:10 250:1,11 250:16,19 251:20 252:2 253:8 255:15,16,19,21 256:1 260:4 275:3 278:11,11 289:9 323:20 330:7 341:7,13 358:1,7 362:6 380:1,2 383:3 384:3 evidence-based 9:14 22:12 239:10 exact 154:16 251:6 335:8 exactly 34:16 36:7 49:3 133:3,8 158:2 183:20 189:5 214:16 228:2 257:14 266:12 335:8 353:18 390:13 examine 181:18 288:19 examined 60:10 example 9:1,6,7 16:22 19:13 20:14 21:3,4,21 41:16 44:19 65:3 100:19 129:9,14,18 131:5 133:10 169:20 205:5 232:17 244:3 267:17 271:20 272:4 274:19 275:17 276:9,19 287:11 290:2 293:2 302:9 303:12 334:17	369:20 374:14 377:8 examples 18:21 19:9 275:8 excellent 153:2 332:4 334:13 337:5 395:10 exception 19:20 345:16 exclude 103:11 122:20 305:22 306:2 307:21 370:17 371:17 excluded 47:17,21 51:21 91:1 129:11 130:12,21 190:6 190:12,15 235:16 320:14 371:1,8 excludes 123:1,7,9 305:14 354:7,17 excluding 32:21 160:6 302:17 exclusion 29:16 112:14,17 113:2,3 129:7 130:7 201:17,19 333:17 333:17 371:11,13 372:1,6 374:22 exclusions 10:13 17:6 23:12 90:13 196:22 201:7 284:8 303:21 304:20 305:12,12 306:9 372:8,13,14 exclusive 140:7 Excuse 149:6 exercise 153:20 269:14 271:6 355:17 exist 184:9 205:1 229:15 230:4 368:12 existed 164:22 existing 341:16 exists 141:22 243:10 expand 204:6	expect 118:3 137:22 283:13 318:21 expectation 186:14 244:13,19 expected 42:11 79:6,8,8 93:10 116:1 132:7 156:2 172:8 173:11 185:19 186:7 187:15 261:2,3 262:1,3 311:8 343:19 expecting 239:17 321:3 expenses 373:9 expensive 40:2 148:3 experience 63:17 63:21 64:2 138:13 384:17 388:14 expert 29:5 62:15 218:13 292:4,16 309:7 340:20 341:16 349:9 361:15 362:2,3 expertise 15:3 278:3 382:2,16 experts 105:4 113:6 130:14 397:4,7 explain 42:12 86:16 170:9 340:19 explained 135:18 explaining 43:14 explanation 67:13 168:2 180:11 184:14 explanatory 45:3 48:19 60:8 67:15 108:17 explicit 379:21 exploratory 52:14 exponentiate 31:18 expressed 155:6 263:18	Expression 4:13 extensive 98:8 374:19 extent 30:10 116:14 195:21 218:14 236:1,17 274:2,10 336:14 345:15 external 372:13 extra 358:13 391:7 extract 346:4 extraction 276:9 extreme 132:19 extremely 14:19 35:10 110:21 111:7 120:16 206:10 300:8 326:10 372:14 385:19 extremes 62:5 eye 264:22 352:11 eyes 214:2 <hr/> F <hr/> FAAHPM 1:20 FAAN 2:3 face 29:4 100:14 101:13 104:22 213:20 300:19,22 366:20 facilities 145:13 193:18 198:18 199:3 268:15 345:3 facility 111:13 123:3,14 140:9 147:22 148:1,19 266:22 268:20 298:6 329:14 334:15,17 344:3 356:17 facility-level 267:12 268:11 298:7 341:22 360:11 362:16 FACS 2:9 fact 34:17 35:11	40:7 41:10 45:3 45:10,15,16 48:16 49:22 53:10 54:16 55:18 73:20 74:3 80:9 87:20 91:8 115:14 134:17 136:2,13 138:7 162:13 163:10,17 165:6 172:6 180:16,22 204:3 230:3 233:15 251:18 256:11 289:22 310:8 321:14 329:4 332:10 351:17 355:15 370:16 382:9 factor 38:12,13 41:20 46:19,21 48:18 117:14 136:16 141:15 201:11 223:21 388:12 factors 9:19,20,22 10:12,17 14:3 15:4,6,8,9,22 17:6 19:3 38:16 42:10 42:17 59:20 60:2 91:5 108:13 136:13 137:1,3,4 137:22 141:10,21 142:2 149:19 155:2,18 158:8 159:2 160:5,6,9 160:13,19 163:20 164:6 165:10,11 165:12 166:11,19 166:22 167:9,17 168:2 174:7,22 176:3,22 180:15 181:12,21 182:16 182:21 184:13 186:2 263:5 306:15 fail 88:3 failed 172:2 175:8 195:22 200:22
--	---	---	--	--

failure 25:5 99:13 110:1 151:18 156:21 157:10,10 172:2 293:9,10 295:15	294:2 310:10 feel 66:16 75:11 83:12 131:7 153:14 173:3 223:16 258:6 295:2 328:13 343:3 346:16 350:4 359:4,16 375:6	financial 115:20,20 154:14 find 45:7 46:20 61:7,18 62:11 79:19 100:4 101:2 104:11 137:11,18 150:21 171:8,15 171:17 177:12 184:4 238:11 243:20 279:18 280:6 323:9 354:18	firstborn 280:11 fit 62:5 397:11 five 6:10 118:16 228:9 234:5 283:16 flight 33:15 37:1 116:20 192:15 228:13 Flighted 115:6 flip 314:21 floating 256:6 floor 1:9 251:2 301:14 Florida 1:19 79:2 flow 370:21 fluid 172:1 flutter 360:14 361:10,14 362:1 focus 6:17 60:16 118:8 158:19 208:6 212:11 265:9,12 266:12 270:13,15 271:2 273:3 284:10 286:7 317:4,7,15 330:8 362:4	305:22 306:1 forces 289:16 foregoing 192:7 264:12 398:10 forever 150:7 forget 144:17 211:1 320:18 390:13 forgotten 171:20 form 22:15 28:16 252:4 266:6 307:11 347:21 348:3 365:21 formats 9:5 forms 375:16 Fort 2:5 forth 60:3,14 80:14 240:8 256:17 336:15 Forum 1:1,9 181:7 forward 84:12 89:17 237:7 243:11 255:5 258:12 266:3 272:9,11,14 274:1 299:14 303:10 329:15 345:20 353:17 363:17 377:14 379:20 382:11 384:10 392:16 393:2 Foster 261:18 found 29:17 64:19 126:16 128:16 147:18 171:18 180:5 276:17 294:14 321:12 foundation 1:15 167:21 227:2 foundations 386:10 four 25:17 70:19 91:15 109:12,17 110:3 119:14 121:22 185:11 190:19 195:8 228:8,9 235:3 236:6 261:11,12 261:16 265:6
fairly 65:10 176:7 faith 143:17 150:19 216:2 218:6 fall 45:11 132:9 379:20 fallouts 326:4 falls 369:10 374:4 familiar 109:13 families 53:15 154:10 family 24:22 53:5 54:2 55:20 56:1,7 famous 55:17 fancy 110:9 fantastic 43:16 97:16 far 77:21 89:11 171:9 265:7 285:2 304:7 329:8 376:2 fashion 111:17 fast 356:11 365:5,6 fastest 148:10 fault 150:10 152:19 favor 301:6 avored 309:8 favorite 131:5 FCM 209:18,22 210:2 219:21 fear 392:13,21 feasibility 82:12,13 119:17,19 120:11 190:21 191:6 276:6 feature 310:22 feed 314:12 340:3 feedback 13:9 36:10 185:20	feeling 72:4 113:5 151:10 218:6 296:8 315:14 feels 218:18 251:11 fee-for 115:16 fee-for-value 115:17 Feinberg 2:9 felt 105:4 200:18 201:10,12 258:11 291:19 324:20 fibrillation 362:7 field 138:19 139:4 139:6 140:16 150:17 156:5 213:13 238:1 255:17 307:12 310:9 350:13 364:7 377:16 382:6,11 Fifteen 83:17 127:7 fight 56:8 figure 227:4 316:16 349:11 351:14 353:19 391:5 fill 143:8 239:8 filling 323:19 film 374:17 FIM 238:8,10 final 62:22 100:10 121:4 159:14 182:9 183:6 250:14 325:20 352:6 396:18 finally 16:8 32:18 121:3 198:3 199:15 finance 150:8	finding 165:9 178:9 findings 236:12 261:20 finds 137:1 fine 82:1 188:5 252:5,8 358:12 359:12 finish 69:20 fire 386:8 firefighter 389:7 firm 389:9 first 5:9 14:12 18:12 20:19 21:2 21:8 22:9 25:21 34:5 84:14 93:22 98:1 102:2 112:15 114:2,11,13 151:5 157:17 160:10 162:14 163:2,2 173:18 183:10 192:13,16,19 196:12,12 204:15 224:12 233:17,21 241:17 243:15 249:16 258:21 270:3 283:20 293:16 298:2 313:20 318:8,9 328:11 329:10 333:9 348:16 351:10,20 358:19 359:17 370:2 375:18 377:2 381:9 390:1 393:4 395:6	first 5:9 14:12 18:12 20:19 21:2 21:8 22:9 25:21 34:5 84:14 93:22 98:1 102:2 112:15 114:2,11,13 151:5 157:17 160:10 162:14 163:2,2 173:18 183:10 192:13,16,19 196:12,12 204:15 224:12 233:17,21 241:17 243:15 249:16 258:21 270:3 283:20 293:16 298:2 313:20 318:8,9 328:11 329:10 333:9 348:16 351:10,20 358:19 359:17 370:2 375:18 377:2 381:9 390:1 393:4 395:6 Florida 1:19 79:2 flow 370:21 fluid 172:1 flutter 360:14 361:10,14 362:1 focus 6:17 60:16 118:8 158:19 208:6 212:11 265:9,12 266:12 270:13,15 271:2 273:3 284:10 286:7 317:4,7,15 330:8 362:4 focused 144:6 228:2 369:18 focusing 173:13 fold 11:3 folder 62:22 folks 90:18 95:2 129:1 299:13 378:18 382:2,16 384:15 follow 169:2 351:22 397:20 following 4:6,8 85:7 90:4 122:7 122:14 396:2,16 follow-on 130:15 130:16 follow-up 41:8,22 138:3 178:11 311:7 force 19:7 240:18 forced 105:3 255:4	

270:5	fundamentals	20:6 36:21 124:19	125:19 127:11	glossed 307:7
Fourteen 82:19	374:22	216:18 239:1	128:1 159:15	go 8:6 20:18 22:18
120:22	funds 373:4	290:8 292:17	160:12 162:6	22:18 24:4 26:8
fourth 50:18 114:6	further 34:13 92:7	322:8	163:16 167:13	32:17 42:16 46:13
114:9	121:13 133:17	generate 132:20	180:8 182:12	51:7 60:6,13 63:6
four-digit 31:22	140:14 191:17	257:15 325:3	185:14 188:6,12	69:15,19 71:7
frailty 112:19	204:6 218:17	366:21	191:1,11 256:4	77:13 84:4 91:19
113:6	224:21 236:3,19	generated 80:7	279:17 280:3,17	91:20 92:7,9,9
frame 144:1 284:11	249:18 252:7	366:7 371:19	280:22 281:8	93:17 94:13
frankly 377:19	347:10 355:20	generically 147:3	300:4 309:11	102:16 105:21
fraught 382:7	383:8	gentlemen 181:6	311:6,19 312:12	106:22 108:7
Fred 330:20	furthermore 42:5	Geppert 3:7 24:16	381:9	109:1 118:12,13
FREDRIK 2:9	future 31:15 32:15	31:11,12 34:12	give 5:12,18 7:8,18	119:10,13 120:13
free 343:3	74:14 114:19	48:16 60:6 61:5	7:21 9:7 55:21	120:21 121:20
freely 276:10,20	116:5 245:10	61:18 62:9 68:4	84:3 90:1 107:12	124:1,15 127:5,5
frequently 49:15	289:12 297:3	68:14,19 79:19	141:5 153:22	127:16,16,18
240:9	345:6 348:10	280:14,18 281:4	154:15 157:19	135:10 142:1
friend 207:22	361:1 383:12	293:21 310:21	170:19 171:20	143:21 144:20
friends 207:13		311:12 312:1	172:2 196:4,6,11	149:2 154:11
front 300:21 351:8	G	getting 52:20 60:14	197:13 198:22	156:2 159:2
fruitful 279:21	Gail 1:20 57:12	111:13 175:21	216:8 242:4	160:18 162:9
Frymark 192:22	78:22 112:12	205:5 206:4	244:18 264:17	166:9 169:5 172:1
FT 293:3	188:17 248:20	212:12 220:1	277:19 278:18	172:22 187:6
full 87:10 141:11	268:17 368:12	232:20 241:10	280:10,15 281:3	191:21 192:18
141:18 200:9	gains 194:17	308:10,12 320:4,8	284:5 287:10	205:3 208:12
337:1	game 303:16	326:11 342:16	304:21 325:17	211:20 215:5
fully 18:22 35:2	gaming 87:22	343:7,12 359:11	327:5 330:11	223:2 228:18
218:7 345:21	gap 26:22 41:2	363:3,5,7 370:14	354:10 357:19	230:19 233:1
351:21	92:13,15 93:13,16	381:5 391:3 398:1	387:20 396:3,5	234:10 235:17
function 30:11	125:18,20 127:1,4	giant 179:20	given 14:18 79:8	236:4 238:6
41:22 240:17	143:7 178:20	268:12 302:21	116:3 129:7 132:6	240:14 249:6
244:2 246:20,22	324:10,11 341:16	GIDWANI 1:22	134:16 156:2	250:18 264:22
247:5,7 253:21	344:22 385:6	31:2,14 32:8 33:8	163:17 164:21	269:7,13,22
369:20	gaps 4:21 363:22	36:15 37:13 38:8	171:22 180:16,22	270:22 271:5,14
functional 4:9,10	garbage 331:4	38:14 52:6 53:3	187:15 203:2	272:14,15,18,20
4:11,12,13,14,15	337:22	53:21 54:12 60:18	239:21 249:10	273:18,19 274:11
4:17 63:18 194:17	gathered 120:3	61:1,14,22 66:20	261:13,13,16	276:18 279:7
200:13 211:3	GEE 30:1	67:5,8 68:10,17	269:8 284:7,11	283:15 287:2
369:9,15 385:8	gender 10:21 23:16	69:1 71:17 79:13	309:11,16 368:19	290:13 291:8
functionally 223:10	30:2 92:17 201:3	79:17 80:1,15	373:4 383:3	292:12 295:8
Fund 71:9	general 2:14 24:10	81:16 83:9 89:21	gives 39:18 167:8	301:2 303:10
fundamental 295:3	28:5 146:20	92:4,14 94:1,18	296:11 345:18	305:9 314:20
324:19 332:18	255:22 293:11,13	102:1,11 104:3,13	giving 134:10	321:4 326:17,17
391:11	309:2,7 338:14	104:16 106:4	204:18 239:2	327:16,16,19
fundamentally	355:6 356:7 360:3	114:2,8,16 118:19	317:11 333:8	348:14 352:9,15
337:2 355:12	generalized 14:12	119:18 121:5,10	glad 7:6	353:11 355:20
359:13	generally 19:15	122:11 123:18	global 215:19	356:11 358:17

360:7 362:12	205:18 206:1,10	139:8 140:13	greatest 25:21	239:11 301:15,16
363:10 376:8,10	215:16 219:11,14	143:6 149:3,16	greatly 164:10	group's 126:22
377:6,9,12 379:16	220:17 221:17	152:17 163:2,6	Greg 73:11 109:1	grow 255:2
379:19 382:21	229:21 233:22	167:4 169:22	124:16 333:12	growing 151:15
387:19 391:1	234:12,21 235:10	170:2 181:3	372:11	153:12 184:8
393:2,17 394:2	237:9 238:6	192:20 199:9	Gregory 1:25	guess 15:21 26:8
395:12,17 396:12	241:20 242:12	218:6 225:4 230:3	370:3	45:2 46:2 50:18
396:17	244:9 245:13	250:14 254:3	group 3:18 25:16	64:8 100:13
goal 8:20 113:18,21	247:21 248:3	260:7 272:19	25:17 26:1,14	101:12 124:11,12
138:18 166:17	257:14 264:16,16	277:6 290:16	28:3 30:19 31:1,5	134:8,20 141:19
256:20 289:12,17	264:22 266:14	291:21 300:18,22	40:9,10 64:14	142:3 143:15
339:4,9 340:7	267:18 268:13	303:3,19 317:1,17	71:1,13,18 82:14	147:10,10 151:19
393:15	273:2,15 279:13	332:1 363:9,18	83:1,2 87:10	161:4 168:3
goals 55:3,9,12	279:15 281:11	387:4	91:14,15,17 93:8	186:19 204:17
56:13 140:14	283:16,19 287:7	gosh 300:20	93:12 94:2,3 95:1	207:3 214:11
God 45:15 299:21	287:17 290:1,3,6	gospel 135:7	116:22 117:7	215:9,20 219:1
goes 41:19 116:10	290:15 294:15	gotten 313:3 316:8	118:20 122:8	224:15 225:13
148:19 188:9	295:10 296:19	343:13 363:19	126:7,7,21 127:12	232:5 234:9,17
223:19 368:9	297:18 298:12	government 74:9	128:2,9 151:9	237:5 238:5 241:6
going 5:8,9,10,12	300:6 301:5	75:7,19 253:4	165:7 166:9 169:9	242:21 244:22
5:14,18 6:2,19 7:3	304:16 316:20	go-around 381:15	170:19 185:15	246:4 250:15
7:18 8:2 11:5,9	320:14 322:5	grab 168:21	189:15 191:12,13	251:1 252:17
12:15 13:14 17:13	326:3,17 331:11	gradation 134:13	191:16 200:3,6,8	258:18 274:12
17:15 22:19,21	331:14,21 336:20	grading 134:17	200:15,18,22	280:5 296:11,22
30:19 48:3 56:15	338:16 339:6,8,17	grant 329:18	201:10 204:2	299:9 301:22
56:22 57:7,16,19	344:3,8 350:21	granted 247:6	213:1 218:4,12,18	315:13,18,19
58:22 59:2 61:5	356:11 373:1	267:21 299:15	219:19 229:19	321:21 324:7
62:4 66:18 74:7	381:2 382:3,4	granular 339:14	231:16 232:2,8	325:3 328:11
78:6,17 81:6	386:5 388:8,15	granularity 322:12	233:15,18 235:3	339:17 346:12
84:19 85:19 91:10	394:2,13,16 395:4	grasp 77:19 78:16	241:19 248:4,6	352:16 357:14
98:21 100:3	395:14 397:4,8,15	gray 56:13 295:12	249:7,13 283:16	379:20
103:17 108:9,15	gold 29:9 39:19	great 5:6 25:15	290:8 291:18,20	guessing 179:21
110:17,18 111:22	40:4 42:19 95:9	32:8 46:12 61:17	292:16 314:21	guest 281:7
114:17 115:1,6	95:15 367:13	69:9 75:20 92:12	328:7 337:21	guidance 17:18
130:8 135:10	Goldfield 3:8 34:6	106:16 169:12	349:17 352:9,10	117:10 158:5
138:16 139:8,11	34:12,14 35:6,7	196:16 214:4	352:12 358:16,17	197:22 218:11
145:17 146:11	35:19 36:1 53:7,8	226:8 232:6	358:19 362:13	249:9 383:4
153:4,21 155:1	54:3	254:16 281:9	382:22 383:2,2,15	guideline 361:16
167:22 171:2	good 5:3 6:4 7:4,5,7	288:12 291:13	383:17 386:13	361:17,19
173:2 175:1,2	19:14,17 24:9	309:21 313:2	392:14 397:18	guidelines 40:9
176:21 178:19	27:22 29:10 31:2	345:5 352:8	398:7	44:20 80:8 239:12
179:11 183:20	36:22 58:8 66:13	355:14 364:6,17	grouped 104:12	263:2 316:4,15
184:13 187:6	74:2,16 75:9	377:22 380:12	180:3	365:15 367:6,19
188:15 189:12,15	78:20 80:1,6,16	398:7,7	grouper 99:22	guilt 55:22
192:4,12,14	88:3 105:15 111:4	greater 33:21	100:1 103:8	gut 349:21
196:10 199:19	120:16 124:7	136:16 238:12	279:19	guys 196:9 198:11
200:14 203:8	130:5 131:6 137:1	288:4 301:18	groups 30:6 165:8	227:14 264:3

270:8 281:21	110:14	330:6 333:3	90:1 110:4,5	hemorrhages 45:4
283:13 284:19	handy 61:7	337:19 340:22	111:2 124:16	46:9 285:13,19
322:3 353:12	HANLEY 3:9	351:20 360:16,21	147:2 169:9 291:9	hemorrhagic 23:11
359:4 363:16	happen 54:15	363:16 380:15	309:6 348:15	41:17 58:16,19
376:4 378:3,17	60:12 117:17	394:11	373:1	59:19,22 80:5
385:3 394:13	170:16,17 175:3	harmonize 296:9	heard 78:2 121:18	81:6 288:17
396:5 398:5	176:21 219:21	304:1 324:4	294:2 304:6 349:5	290:22 291:17
Gwen 308:18	220:5,18 224:3	harmonized 16:15	351:1,17	292:7 293:22
GWENDOLEN	348:9 367:3	17:7,12 265:18	hearing 3:17 13:9	294:5 295:4
1:19	369:22	268:6 273:5,7,11	172:13 239:15	298:17 299:2
	happened 5:13	274:10 313:11,15	312:20 325:13	Herrin 3:10 84:15
	49:15 61:6 72:13	319:17 336:15	337:18 350:13	160:10 162:10
H	221:6 234:19	345:15,18,21	heart 25:4,5 40:9	hesitancy 253:15
habits 323:18	249:15 369:6	350:15 361:3	151:18 156:14,15	254:22
HACKNEY 1:23	383:8 388:14,16	harmonizing 324:2	156:18,19,21	hesitant 253:2
57:16 364:9,19,22	happening 135:14	376:3 394:7	157:9 172:2	heterogeneity
383:22	136:5 163:14	hate 249:3	217:20 293:2,9,10	169:18
hairs 204:11	359:22	Haven 3:2,5,10,13	295:14 301:3	heterogenous
half 25:22 137:14	happens 44:4,5	3:15	held 168:3	291:20
137:15 214:4	49:14 75:21 102:4	head 6:10 39:7	Helen 2:13 20:7	hey 351:9
217:2 223:17	153:9 154:17	388:18	69:2 118:1 157:15	Hi 84:6 113:12
242:2 254:4	162:19 163:12	headache 378:17	169:13 217:9	291:6
261:22 264:8	177:9 350:1	heads 8:14	251:13 267:13	hidden 373:14,16
348:22 349:6,19	383:14	head-to-head 8:10	269:16 283:1	374:6
366:6 388:22	happy 160:18	health 1:13,17,21	312:13 344:13	hierarchical 11:21
392:13	272:1 381:13	1:25 2:12 3:3,6,8	348:13 376:9	12:1,18 13:3,13
HAMMERSMIT...	hard 8:13 11:4	3:10,13,15 25:9	helicopter 34:4	14:10 29:22 85:15
2:14	35:16 73:16 103:9	47:14 66:6 71:11	help 5:19 66:18	91:6,7,12
Han 84:15	104:22 134:21	82:15 89:10 92:5	182:6 207:16	high 25:18 26:2,5
hand 5:10 6:2	143:5 176:14	120:7 124:18,19	218:7 274:13	26:22 27:10,19
22:19 71:15 76:1	184:17 280:6	124:20 125:6,9	354:2,11 375:1	28:6,9 43:3 65:9
76:2 152:19,20	292:3 354:18	153:6 158:14	376:8 382:11	65:10 70:18 71:2
199:20 201:15	367:19	179:4,17 180:2	helped 188:17	82:9,14,19 91:17
228:5 230:10	harder 258:8	230:13 232:16	383:19	91:21 93:14,19
288:2 333:12	269:12	240:17 241:4	helpful 13:16 29:21	94:14 95:4 106:7
381:7	hardest 377:19	244:2,13,14 254:7	135:20 158:6	106:10 107:5,5,17
handed 284:17	Harlan 3:13 168:9	256:1 258:9	235:9 279:13	113:10 118:15,21
handle 49:12,12	169:1,7	261:17 262:13	302:15 376:20	119:14,21 120:22
99:16 117:2 305:5	harmonization	335:15 350:17	383:11 393:7	123:20 124:8
handled 19:12	4:21 265:14	373:14 390:12	helping 170:3	127:1,7,13,19
306:21 307:2	267:16 269:19	392:2	helps 143:8	171:15 185:16
360:2	274:2,18 278:5	Healthcare 2:10	hematoma 41:18	190:18 191:2,7
handles 78:2 81:17	282:8 287:3 297:2	3:4,22 24:14	hemicraniectomy	201:11 202:10
handout 283:22	297:7 298:12	hear 5:14 6:20	129:19	206:10 211:7,9,17
284:5 314:22	299:12 300:2,6	17:20 35:17,19	hemiplegia 103:19	228:8 236:6
hands 167:10	301:5 304:16	60:20 65:13 73:1	hemorrhage	295:18
254:15	311:4 319:22	73:16 79:14 84:21	299:19,19	higher 19:4 32:22
handwriting				

33:16 38:17 45:5 58:21 59:1 79:6,7 92:22 93:2 115:4 115:7 126:18 132:1,7,16 142:4 145:18 172:7 173:10 186:7 211:21 242:15 261:2,22 262:1 269:5 292:8 308:16 326:1 327:7 342:3 highest 259:20 308:8 highlight 20:5 highly 40:5 57:22 95:12 high-impact 207:1 210:13 212:7 high-level 11:10 286:8 high-quality 45:19 230:6 high-risk 306:17 historical 85:14 87:21 101:2,10 298:21 historically 99:11 172:7 253:3 history 48:7 99:12 102:6 104:6 hit 119:12 176:20 hits 95:11 hold 22:4 247:21 389:17 holes 355:6 home 44:13 115:9,9 138:14 150:4 171:18,19 172:1 172:22 177:8 322:22 327:4,11 327:16,17 homework 283:11 honest 303:9 honestly 64:9 375:15 hope 41:3 73:18	269:11 364:11 373:16 379:10 hoped 233:22 hopefully 179:12 270:19 280:21 372:17 380:12 hoping 40:14 102:13 378:11 horrible 385:20 horse 336:20 346:17 382:21 Hosmer-Lemesh... 62:7,16 hospice 1:20 90:20 112:15 113:1,17 hospital 4:5,7 13:21 23:8,9,13 25:7,11 26:1 27:5 27:7 29:14 41:13 43:6,20 44:4 46:7 46:9,10,11,15 47:13 48:21 49:18 49:19 50:20 53:13 53:14 54:16,18 58:15,17,17 64:17 65:8,12,21 72:9 72:10,14,14,15,17 74:12 76:19 77:20 78:17,18 79:5,7 81:7 85:7 86:2,2 86:10 87:2,11 88:4,12 89:3 90:15 91:10 94:9 95:10,20 96:13,15 97:3 100:6,8 102:4,6 107:11 111:15 122:6 123:5 125:22 130:3,5 131:18 132:1 133:15 135:15 136:12,16 137:3,11,13,15,16 140:5,21 141:21 143:12 147:17,19 148:5,7,13,16,18 150:7,10,18 151:4 151:5,15 152:22	153:15 154:1,2,7 154:19,21 155:3 155:19 156:12,14 156:15 157:3,7,22 159:3 162:14 163:1,3,8,14 164:8 165:20 166:1,11 167:9 168:1,18 169:17 170:7,17,18,19,21 176:2,15,18 178:21 179:2,6,9 181:13 184:13 186:6 187:16,17 187:17 188:7 189:10,14 261:9 286:11 289:19,21 290:2,4,6 292:22 293:8,15 305:15 305:17 306:6 307:14 308:14 313:20,22 315:7 315:11 323:15 332:9 334:20 338:8,14,17,20 339:12,13 343:17 343:22 344:6 347:3,22 348:4 356:22 359:9 366:8 371:5,6,8 372:7 379:7,9 384:18,21 386:2 386:12,19 387:9 393:8 HospitalCompare 260:21 hospitalization 4:6 4:8 85:21 90:5 122:8,15 145:4 146:16,19 175:3 188:18 314:4,9 319:1 339:12 hospitalizations 314:5 hospitals 11:15 13:20 25:10 29:17 32:22 33:3 39:17	42:13 44:9,12 47:12,16 49:11 50:21 51:3,3 52:19 58:1 59:5 64:19,21 66:5 73:7 75:8 78:21 82:2,5 86:19 88:19 93:6 96:9 97:4 105:21 113:14 116:17 126:17 134:18 135:17 138:7,20 139:5,10 141:10 141:15 143:11 144:2,5 145:1 146:9 149:16 153:8 154:4 155:21 156:1,4 162:13 163:21 167:1 168:22 172:11 173:8,10 177:12,19 178:13 183:2,3 186:16 187:13 261:15 262:1 302:5 309:19 310:2,12 334:9 336:1 339:9 342:10 344:4 347:12 350:17 367:11 368:22 370:17 371:14,16 372:5,17 379:1 386:12 hospital's 72:11 73:8 78:2 107:7 107:16 136:4 150:10 173:7 175:5 hospital-based 297:14 338:22 359:7 hospital-level 44:1 48:17,20 122:13 160:1,6,9 161:1 163:20 164:6,17 164:20 165:10 167:16 168:5	180:15 182:16,21 186:2 267:20 268:5 274:5 hospital-specific 13:22 hospital-wide 189:7,9 hour 133:21 222:10 264:8 388:22 hours 158:4 197:16 197:17 223:18 231:7 236:15 237:22 242:15,16 254:4 365:10 How's 97:2 HSC/Jacksonville 1:19 huge 217:20 240:18 247:15,16 260:15 329:1 392:1 Humana 2:9 hunch 347:1 hundreds 104:15 hurt 66:18 78:21 149:15 hypertension 100:19 101:4,19 301:4 hypothesis 245:16 245:18
I				
ICD 120:8				
ICD-9 90:12 103:7 103:10,14 104:15 109:12 110:7,21 180:4 299:22 366:21 367:8				
ICUs 55:1				
idea 20:12,15 167:22 274:16 318:14 324:1 337:19,20 338:7 339:19 370:5,10 387:21				
ideal 269:2 288:20 345:12				

ideally 63:18 335:5	224:22 225:5,15	162:3 165:14,21	206:7,11 207:9	318:3 340:18
ideas 300:1 311:4	226:1,4,18 227:9	166:21 167:18	208:5,5 219:20	371:2
364:2,5	228:6 232:22	173:15 182:3	243:5 246:19,21	inclusion/exclusion
identification	233:20 235:17	187:10 189:10,13	316:10 326:9,13	374:20
39:14 188:2	236:1,4,5 238:3	194:7 195:18	333:4 346:9	income 158:18
identified 15:8 19:1	239:5 242:7 263:6	199:16 225:9,13	392:12 393:17	inconsistent 90:16
266:16 314:18	275:3 352:3,5	226:16 227:16	improvements	incorporate 41:11
376:12	365:4,18 379:2,17	248:10,14 251:16	64:22 138:9	incorporated 388:6
identifies 373:16	380:11,12 381:21	254:18 258:12	improves 243:9	incorporating
identify 11:2 13:16	384:3 392:18	263:5 267:8,11,16	improving 379:10	53:19,22 54:1
16:14 17:11 20:3	impacted 54:8	268:2,6 286:10,18	inability 181:2	incorrect 218:15
33:7 56:22 133:16	impacting 145:16	287:14,19 302:18	240:8	increase 166:12
187:12,13 232:14	241:5	307:5 326:10	inaccurate 201:21	172:5 201:5
306:14 375:9	impacts 232:16	330:14 333:1	inappropriate	increased 223:20
identifying 7:17	244:11	342:7,20 363:12	320:19	225:9 277:11,16
188:2 376:6	impaired 223:10	364:13,16 368:5	incentive 148:7,9	increases 92:20
iffy 271:21	imperfect 110:12	385:20	incentives 48:10	222:22,22
ignorance 368:2	110:22 111:7	importantly 88:16	incidence 93:1	increasing 144:7
377:1	136:14	131:12	include 15:10 30:2	186:12
ignore 155:1	Imperial 261:19	impossible 57:19	53:1 63:16 98:14	incredible 389:3
ill 175:7	impetus 194:13	131:14 263:15	99:3 105:5 117:15	incredibly 155:16
imagination 151:14	implementation	268:1	130:18 160:21	index 98:12 99:3,8
Imagine 263:3	117:4	impression 44:18	164:5 294:11,18	99:14 190:9 314:8
imaging 364:10,16	implemented 48:9	384:1	311:21 319:10	314:10
365:5,16	49:7,8 73:21	impressively	330:2,4 333:11	indicate 19:18
immediate 348:9	173:1	138:10	361:13	134:3 170:1 239:4
immediately 77:16	implements 311:1	imprimatus 76:1	included 15:5	303:16
immense 170:5	implication 116:4	improve 65:15	18:20 30:14 39:9	indicated 289:8
impact 24:2,3	implications	138:12 168:1	48:14 90:15	320:20 330:2
25:14 26:4 28:19	191:19	170:3 171:16	102:22 103:1	indicating 89:9
75:18 76:5 91:16	implicit 143:10	177:2 186:10	112:20 131:3	309:17
91:19,20 107:7,17	144:1	189:16 220:17	142:2 160:20	indication 98:15
123:17,19,22	implies 76:18 77:2	221:1 223:21	161:2 167:17	222:4 258:16
124:1 148:16	136:12	238:22 248:12	196:17 204:4	indicator 34:11
149:14,22 184:9	implore 299:17	295:20 323:14,16	229:9 263:19	205:16 336:8
196:18 197:9	importance 57:17	342:21 393:1	342:14,19 364:15	indicators 99:5,21
200:17 201:11,11	63:9,10 151:20	improved 67:14	includes 9:4 14:2	100:5 345:10
201:12 202:10	228:15 275:4	164:11 221:8,10	18:16 30:6,8	indirect 81:5
203:11,16,17	important 18:17	224:6 231:11	188:9 307:13	individual 35:13
204:7,11 205:10	40:7 41:20 49:22	247:2 380:1	328:17	36:6 87:4,7 88:2
205:12,21 206:1,4	60:19 69:6 81:1	improvement 8:20	including 10:17	100:2 103:9
206:6 207:4,6,10	87:5 89:5 103:21	26:21 65:17 70:2	42:16 108:13,17	163:12 237:12
207:17 208:19	105:5 107:13	71:10 138:5 143:3	108:20 118:7	339:7 344:10
209:12 210:15	116:3 131:7,22	163:8 167:21	158:9 309:9	347:14 388:8,9
214:3,6,10 215:17	138:8 143:2	189:18 194:19	340:21	individually 16:10
217:21 218:13,20	151:21 155:8	198:14 200:22	inclusion 60:8	21:15 143:1
219:11 223:9	156:7 158:21	204:12 205:7	164:16 191:17	212:17

individuals 36:9 206:20	infrastructure 269:11	38:16 150:1	220:13	291:1 293:22
industry 208:21 209:10 221:3 255:5	inherent 250:6	integrated 384:19 384:20 389:2	intervened 186:3	294:4 295:4
inequalities 10:18	inherently 6:21 247:18 338:7	integrative 240:18	intervention 214:6 220:4,14 223:19 224:2,5 232:15 236:15 295:19 387:18	298:17,18 299:2 299:18 330:17 337:3,3
inevitable 113:11	initial 108:10 145:22 194:13 244:10 296:3	intellectual 382:14 382:18	interventions 169:17,19 178:2,5 178:22 183:2,16 184:2,10 186:13 224:3 225:22 229:14 231:10 239:4 240:20 244:7 245:15,16 247:14	isolating 203:14
inextricably 306:7	Initiated 6:12	intended 391:1	intracerebral 299:18	isolation 324:8,19 332:6
infection 104:6	Initiatives 323:13	intensive 128:2 133:18	intra-class 43:22	Israel 1:23
inflate 82:4	inordinate 83:6	intensivists 109:13	intro 196:5	issue 11:20 31:1 37:12 38:10 46:6 53:1 56:11 58:13 70:14,16 72:7 75:10 81:1,17 99:17 106:21 115:1 117:3 152:18 158:21 159:10 164:2 169:12 170:11 182:20 201:3 211:10 218:4 231:17 267:16 292:15 296:22 302:2 306:18 324:19 331:12 336:6 341:18 345:16 346:1 356:8 365:14 371:21 376:14 384:5 392:2
influence 9:20 10:12 134:19 141:4,5,7,11,12 141:15 144:2 149:19 154:9,14 155:2,20 167:10 168:5 171:10 176:19 177:1 178:2,5 339:19	inpatient 16:21 25:1 42:22 43:5 43:15,18 44:2 85:11,12 158:12 274:9 286:1,19 287:13,21 288:2,6 289:10 304:11 305:20	intent 129:8 145:3 145:10 209:16,18 210:8	introduce 44:6 84:4 149:17 287:8	75:10 81:1,17 99:17 106:21 115:1 117:3 152:18 158:21 159:10 164:2 169:12 170:11 182:20 201:3 211:10 218:4 231:17 267:16 292:15 296:22 302:2 306:18 324:19 331:12 336:6 341:18 345:16 346:1 356:8 365:14 371:21 376:14 384:5 392:2
influenced 206:5	input 116:21	intention 341:4	introduced 52:12	302:2 306:18 324:19 331:12 336:6 341:18 345:16 346:1 356:8 365:14 371:21 376:14 384:5 392:2
influencing 207:11 294:21	insane 350:16	intentionally 303:7	introduction 29:21 98:9 264:17	371:21 376:14 384:5 392:2
influential 142:22	inspect 34:22 35:2	interact 374:2	invalid 355:17	issues 5:20 7:14 11:22 12:4,21 14:16 62:4 69:5 121:18 132:9 154:4 211:7 221:8 223:4 252:1 256:6 260:11 265:4 287:3 303:6 306:13 314:17 346:8 352:19 363:15 369:3,19 390:18 395:22
inform 249:18	instance 145:6 370:14,20 371:9 371:19	interaction 59:11 78:12	invested 380:19	260:11 265:4 287:3 303:6 306:13 314:17 346:8 352:19 363:15 369:3,19 390:18 395:22
information 3:9 5:19 13:22 15:16 17:18 22:16 29:12 30:12 36:17 39:21 40:13,15 41:11 54:4 83:3,11,14 87:20 89:3 92:16 96:14 121:13 123:11 125:21 134:9,22 136:7,14 137:18 163:21 164:17,20 197:10 202:13 204:19,21 216:9 230:1,21 236:15 242:4 249:14,17 281:5 282:20 284:6 306:4 307:6 316:2 323:9 325:18 342:8 344:19 345:22 346:4 383:5 384:8 393:7 396:11	Institute 1:13 3:8 24:17 89:10 262:13	interest 168:7 380:15	invested 380:19	260:11 265:4 287:3 303:6 306:13 314:17 346:8 352:19 363:15 369:3,19 390:18 395:22
	insights 157:20	interested 73:5 75:2 240:16 325:15 369:9	investigation 167:8	items 15:21
	inspect 34:22 35:2	interesting 38:15 49:6 113:4 199:17 372:14 380:7	involved 20:9 377:3	it'll 9:17
	instance 145:6 370:14,20 371:9 371:19	interests 278:20	in-hospital 122:21 260:2 262:22 263:11,13 310:5	i.e 120:2
	Institute 1:13 3:8 24:17 89:10 262:13	internal 292:15 327:3	IRENE 3:12	
	instituted 172:8	internally 25:11 251:21	irrelevant 129:10 168:11	
	Institutes 2:11	internist 24:11 251:21	ischemic 4:6,8 23:10 44:22 45:5 58:12,15,18 59:19 59:22 80:4 85:7 90:4,9,22 109:7 109:19 110:1 122:8,14 145:8 146:1,15 147:8 263:1 285:13,14 288:5,16 290:22	
	institution 171:15	interpret 31:18 57:20 101:7 185:18 210:13 242:2 277:20		
	institutional 57:1	interpretability 186:21 279:1		
	institutions 48:10 388:9	interpretation 365:6		
	instructions 141:13 169:21 182:1 280:21	interpreted 366:9		
	insufficient 27:20 28:14 29:2 70:19 71:3,20 82:10 83:11 95:3 118:16 119:1,7,8 128:7 151:9 182:13 185:11,16,17 228:9 236:7 245:7	interrupt 13:7 136:10 149:7 241:14		
	insurance 37:11,19	interval 105:7 188:9 195:20		
		intervene 186:17		

J 3:7 101:17 190:3 202:9 210:12 212:5 243:17 285:22 318:13 333:14 334:21 343:5,16 344:4	290:18 291:4 292:9 294:9 295:8 296:5 297:11 298:4,14 299:6 300:1 301:9,20 303:13 305:9 308:18 309:10 311:3 312:13 313:2 314:20 318:4,7,12 319:2 319:8 321:4 322:13 323:22 324:6 325:5,12 326:16 327:18 328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	362:14 Jolynn 2:7 56:16 57:17 71:15 111:10 177:20 245:12 346:11 Jordan 1:21 241:17 254:3 JOSEPH 3:12 340:10,14 347:9 348:5 361:8,12 Journal 261:8 361:19 judge 81:11 208:16 240:10 judging 113:14 143:12 290:2 judgment 70:9 218:14 249:12 258:5 278:4 383:4 JUDITH 3:15 Judy 84:16 juice 27:17 juicy 23:18 July 369:17 395:17 396:22 397:15 jump 30:20 340:15 jumping 223:14 JUNE 1:6 junior 111:1 justification 272:7 276:21 justifications 278:9 justified 265:21 266:4 269:18 286:14 justify 134:21 239:17 287:20 J.D 2:14 3:7	258:1 343:11 344:2 392:7 KAPINOS 1:25 20:18 22:3,8 54:19 73:12,17 109:2 124:22 321:2,5 351:7 357:22 366:17 370:4 393:19 KAPLITT 2:1 46:1 47:4 48:1 58:6 59:14 80:20 81:21 129:5 132:10 133:9 152:1 153:17 203:6 205:4,19 206:13 206:16 215:7 216:6 219:1 226:20 247:9 257:5 294:10 320:5 321:19 324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3 Kaplitt's 78:5 Karen 2:15,17 3:13 5:15,15 13:6 18:4 18:5 22:18 38:11 41:14 52:21 85:17 108:7 183:6 192:13 200:2 202:14 204:8 218:20 221:12 225:11 228:18 230:10 232:6,11 237:17 243:1 250:13 274:13 281:13 283:1 289:4 312:13 316:19 317:5 348:13 353:20 376:9 Karen's 264:16 369:18	KATZAN 3:12 keep 9:2 69:7 108:12,19 130:4 150:6 303:9 331:14 336:21 337:22 345:13 380:21 398:1 keeping 298:16 343:8,12 352:11 KENDRA 3:9 Kessler 1:15 key 23:15 104:1 144:6 177:16 keypad 18:9 259:7 395:1 kidney 157:10 kind 8:14 13:16 40:15 41:4 64:4 108:19 132:2 134:11 147:2 167:11 178:20 184:4,17 185:2 204:10,13 215:8 226:17 235:18 249:4 254:6 269:15,20 277:21 303:8 315:21 319:19 328:20 340:19 352:19 375:2 376:17 378:5,12 379:5,10 391:4 Kindred 2:10 kinds 145:4 168:14 176:9 208:3 211:16 214:13 289:9 369:11 386:10 know 5:5 8:13 9:10 11:4 12:7 14:21 14:22 15:13,21 16:11,20 17:8,14 17:15,22 19:6 20:8 21:12,17,20 23:20 25:19 28:2 28:4 37:3,16 39:13,22 40:11
Jack 2:5 156:8 322:13	311:3 312:13	JOSEPH 3:12	370:4 393:19	keeping 298:16
Jane 2:8 199:22 212:14 224:9 233:12 234:14 236:10 249:5 369:4 381:7 382:19	313:2 314:20 318:4,7,12 319:2 319:8 321:4 322:13 323:22 324:6 325:5,12 326:16 327:18 328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	Jordan 1:21 241:17 254:3	KAPINOS 1:25 20:18 22:3,8 54:19 73:12,17 109:2 124:22 321:2,5 351:7 357:22 366:17 370:4 393:19	keeping 298:16 343:8,12 352:11
Jeff 24:16 31:12 47:2 59:13 60:4 280:15 293:21 310:14,18	311:3 312:13	Journal 261:8 361:19	KAPLITT 2:1 46:1 47:4 48:1 58:6 59:14 80:20 81:21 129:5 132:10 133:9 152:1 153:17 203:6 205:4,19 206:13 206:16 215:7 216:6 219:1 226:20 247:9 257:5 294:10 320:5 321:19 324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	keeping 298:16 343:8,12 352:11
JEFFREY 3:7	313:2 314:20	judge 81:11 208:16 240:10	47:4 48:1 58:6	key 23:15 104:1 144:6 177:16
Jeph 3:10 84:15 166:20	318:4,7,12 319:2 319:8 321:4 322:13 323:22 324:6 325:5,12 326:16 327:18 328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	judging 113:14 143:12 290:2	59:14 80:20 81:21 129:5 132:10 133:9 152:1 153:17 203:6 205:4,19 206:13 206:16 215:7 216:6 219:1 226:20 247:9 257:5 294:10 320:5 321:19 324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	keypad 18:9 259:7 395:1
Jersey 1:13	322:13 323:22	JUDITH 3:15	257:5 294:10	kidney 157:10
Jessica 2:21 7:19 284:15	324:6 325:5,12 326:16 327:18 328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	Judy 84:16	320:5 321:19 324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	kind 8:14 13:16 40:15 41:4 64:4 108:19 132:2 134:11 147:2 167:11 178:20 184:4,17 185:2 204:10,13 215:8 226:17 235:18 249:4 254:6 269:15,20 277:21 303:8 315:21 319:19 328:20 340:19 352:19 375:2 376:17 378:5,12 379:5,10 391:4
job 31:6 36:22 71:21 75:9,15 105:15 106:8,11 149:16 166:8 385:20	328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	juice 27:17 juicy 23:18 July 369:17 395:17 396:22 397:15	324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	kind 8:14 13:16 40:15 41:4 64:4 108:19 132:2 134:11 147:2 167:11 178:20 184:4,17 185:2 204:10,13 215:8 226:17 235:18 249:4 254:6 269:15,20 277:21 303:8 315:21 319:19 328:20 340:19 352:19 375:2 376:17 378:5,12 379:5,10 391:4
Jocelyn 1:17 190:2 202:8 210:9 212:4 243:16 318:12 333:13 343:4	328:19,22 330:9 330:20 331:6 333:12 334:6 336:17 337:17 340:13 343:4,10 344:13 346:11 348:13,17 352:7 353:2 354:22 355:10,18 356:10 357:5,14 358:13 359:16 360:5 361:6,11 362:9 363:14 364:17,21 365:22 367:21 369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	jump 30:20 340:15 jumping 223:14	343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	kindred 2:10
Jocelyn's 338:5	369:4 370:3 372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	JUNE 1:6	Kaplitt's 78:5	kinds 145:4 168:14 176:9 208:3 211:16 214:13 289:9 369:11 386:10
John 3:4 24:16 64:13 310:13	372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	junior 111:1 justification 272:7 276:21 justifications 278:9 justified 265:21 266:4 269:18 286:14 justify 134:21 239:17 287:20	324:7 331:7 332:14 338:4 343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	know 5:5 8:13 9:10 11:4 12:7 14:21 14:22 15:13,21 16:11,20 17:8,14 17:15,22 19:6 20:8 21:12,17,20 23:20 25:19 28:2 28:4 37:3,16 39:13,22 40:11
JOHNSON 2:15 5:3 13:6 18:3,10 22:17 196:3 200:5 202:14 203:1 264:19 267:2 269:13 274:12,22 276:16 279:15 281:19 283:9 284:1 285:15,20 286:5 287:15 288:9 289:4 290:5	372:20 374:7 375:3 376:9,21 378:14 381:5 382:19 383:21 384:11 385:10,22 392:5 394:12 395:3 398:5	J.D 2:14 3:7	343:21 344:6 356:20 359:6,20 362:19 374:8 387:3	know 5:5 8:13 9:10 11:4 12:7 14:21 14:22 15:13,21 16:11,20 17:8,14 17:15,22 19:6 20:8 21:12,17,20 23:20 25:19 28:2 28:4 37:3,16 39:13,22 40:11
	join 84:18 joined 192:22 Joint 3:13,20 75:13 315:9,20 316:19 325:5,16 328:1 331:2 334:3,10 340:22 343:9,13 345:8,11 346:2,20 346:22 347:4 353:17 354:1 358:10 360:20	K	Karen 2:15,17 3:13 5:15,15 13:6 18:4 18:5 22:18 38:11 41:14 52:21 85:17 108:7 183:6 192:13 200:2 202:14 204:8 218:20 221:12 225:11 228:18 230:10 232:6,11 237:17 243:1 250:13 274:13 281:13 283:1 289:4 312:13 316:19 317:5 348:13 353:20 376:9 Karen's 264:16 369:18	know 5:5 8:13 9:10 11:4 12:7 14:21 14:22 15:13,21 16:11,20 17:8,14 17:15,22 19:6 20:8 21:12,17,20 23:20 25:19 28:2 28:4 37:3,16 39:13,22 40:11
		KAMP 2:10 144:21 146:5,22 147:9,14 188:15 207:21 220:9 228:17 229:16 231:20 238:5,20 239:14 239:20 252:17	Kaplitt's 78:5	know 5:5 8:13 9:10 11:4 12:7 14:21 14:22 15:13,21 16:11,20 17:8,14 17:15,22 19:6 20:8 21:12,17,20 23:20 25:19 28:2 28:4 37:3,16 39:13,22 40:11

44:17 45:13,17	230:14 232:1,6,13	knowing 58:3	168:9 169:3,6,7	144:7 161:8
46:1 47:7,18 48:6	232:22 233:2,6,10	386:4	169:12	242:12 390:18
48:11,14 49:6	233:20 235:4	knowledge 59:16		leading 50:18 64:1
54:5 55:16 57:4	237:5,10 238:4	Knowlton 1:10,13	L	177:18 369:18
57:21 58:4,6,7,8	239:22 240:6,21	22:21 24:4 25:12	Label 31:22	leads 24:17 260:20
61:20 67:7,9 77:9	242:5,13 244:1	26:3,7,16 27:8,12	Labor 397:16	301:4 309:4
78:19 80:22 81:2	245:4,6,15,17,21	28:7,11 30:22	laboratory 40:15	Lean 73:15
81:5,8,10,12,13	246:5 247:5,13	33:5 35:15,21	Labovitz 2:2 50:13	leap 143:16 144:1
82:1,5 86:19 89:7	250:9,10 253:7	36:14 37:8,17	77:14 147:16	150:19
92:6 98:6,8,11,14	254:10 257:10	38:9,19 45:22	149:11 175:18	learn 64:3 142:15
108:3,20 113:15	268:16,19 284:21	49:1,20 50:12	207:3,15 296:6	learned 87:15 88:5
117:12,22 118:1,2	286:16 288:12,15	51:11 52:5 54:10	336:19 366:2,20	88:9 105:13 179:6
118:9 119:5 129:9	289:10,11,14	56:16 57:12,15	370:5	250:5 349:18
129:13,14 131:15	291:7 293:6,7	58:5 60:13,21	lack 37:2 38:16	353:2
133:12,17 134:8	294:16,17 295:5	61:20 64:6 66:8	63:21 135:5 160:9	learning 64:16 70:2
134:20,22 139:3	296:22 297:6	66:19 69:2,19	164:20 278:5	96:14 105:19
139:21 141:5,17	299:10 300:21	70:12,20 71:14	326:22 393:21	349:19
141:20,22 143:4	301:4 302:17,19	72:5,18 73:11,15	language 4:13,14	leave 47:20 81:10
143:13,15,15,17	304:1,11 309:6,20	75:16 77:12 78:22	158:15 192:11	117:10 130:3
143:19 144:1,4,5	316:9,10 318:20	79:11 80:18 81:15	195:16 200:21	171:12 172:3
146:7,9 147:3	320:22 322:16,20	82:7,11,17,21	207:22 208:20	217:15 228:13
150:3 152:2,3,10	324:8,9 327:11,12	83:8,15,19 111:10	216:16 229:11	248:18 283:18
152:14,19 153:19	328:15 329:7	192:10 199:21	238:3 239:18	326:9,12 341:17
154:3,3,12 157:8	332:17 333:16,17	200:11 201:13	258:6 351:16	led 171:10 330:16
157:9,21 161:7	335:6,10 336:10	202:7,20 203:4,20	large 78:8 100:11	393:15
163:2,8,22 165:15	336:12 338:7,8	204:8 207:2,18	116:4 126:2	left 72:2 220:16
166:15 167:8	339:1,18,19 340:1	209:14 210:9	180:20 210:16	264:2 303:6,15
168:3,19 172:15	340:16 342:8,10	212:3,14 213:19	211:6 233:14	388:22
172:16 176:3	343:1,3,17,19	214:17 215:5	373:14	legal 391:20
178:17 182:4	344:1,11 345:2	217:5,9 218:2,19	largely 324:17	Lein 84:15
183:3 184:12	349:1,8 350:5,7	219:17 220:7	391:22	length 44:8 175:16
187:11 197:11	350:10 352:3,18	221:17 222:20	larger 67:17	197:8 333:17
199:9 204:9	353:21 354:10	223:2 224:9	115:13 218:8	lens 86:21
205:12,21,22	356:4,8 359:13,22	225:11 226:18	largest 130:17	lessons 179:5
206:9,12 208:4	361:16 363:6,7,11	228:4,11 229:2	Lastly 373:13	lest 149:15
209:1,11,22 211:5	363:13,22 368:11	230:9 231:2,13,17	laughing 279:9	letter 263:19
211:9,21 213:8,10	368:11,19 372:10	233:12 234:3,7	Laughter 79:16	let's 22:18 26:17
213:13,15 214:2	373:7 375:12,15	281:13 348:18	139:19 187:22	27:9 48:4,7 58:15
215:18 216:3,7	376:11,16 377:12	350:7 384:13	207:14 235:6	60:13,15 70:16
217:18 218:5	378:5,18 379:13	387:1 388:10	239:19 246:11,16	82:8,18 83:16
219:3,7,8,11	380:21 381:22	389:19 391:13	250:4 350:6	91:19 92:8 93:13
220:2,14,16	384:15 385:2	393:20 398:6	366:19	93:17 94:13
222:10 223:11,21	386:9 387:10	knows 45:15	LAURA 3:21	102:20 118:13
224:4,11,21 225:3	388:3 389:1,14,22	366:14	law 38:6	119:10 120:21
225:19 226:3,5,7	392:14,17 393:10	KOLBUSZ 3:13	laws 154:9	121:20 123:22
226:8,13,22 227:1	396:20 397:10,12	317:6 322:5	lay 89:5 387:6	124:15 125:11
227:18,19 229:5	397:13	Krumholz 3:13	lead 56:20 70:10	127:5,16 129:6,12

129:18 130:1	267:8 268:14,15	130:19 160:17	logical 337:12	300:13,14,15,19
144:20 175:7	269:5 329:4	251:17 328:10	login 34:21 281:1,2	302:12 304:15,16
188:8 191:6,21	350:15 372:6	331:4	281:5	305:6 316:22
192:5,18 207:18	license 34:8	listed 97:19 103:16	logistic 29:22	318:7 325:10
207:19 219:9	Lichtman 3:15	lists 330:4	logistical 37:3 91:6	337:14 344:15
231:18 236:4	84:16	liter 171:22	London 261:19	348:7 349:17
258:21 264:1	life 33:15 37:1	literacy 158:14	long 130:21 379:13	353:13,15 356:1
285:1,3 314:20	50:22 51:1 56:9	literature 11:12	longer 105:20	356:14 358:1
327:20 338:13	77:22 115:5	12:20 53:10 54:6	277:14 286:11	360:8 371:10
350:4 351:10	116:20 223:9,12	89:8 141:22	290:1 342:18	392:11,20,22
352:9 353:10	368:4 369:2 373:9	161:22 183:1	346:1	393:10 396:6
355:20 358:17	lift 335:16	197:10 202:18	long-term 145:10	looked 13:2 27:4
360:7 362:12	light 83:13 173:10	229:12 231:9	145:13 317:14	29:4 45:11 58:9
387:17,20 388:1	177:13 349:1	243:20 244:4	long-winded	59:4,17 64:22
level 19:5,5 25:19	lightly 182:7	literatures 250:10	221:14	72:8 86:8 126:6
33:12 35:13 36:8	likelihood 41:21	little 5:10 6:17,20	look 7:16 12:11	126:13 136:21
43:6,21 55:8,11	135:13 175:1	7:2,8,19 9:7 10:10	13:15 14:20 16:10	149:21 157:18
57:1 59:6 81:13	222:14 223:1	11:10 20:8,11	21:14 25:1 28:18	174:14 221:14
85:8 88:12 89:18	limitation 307:3	28:21 35:18 45:21	36:18 42:21 43:21	282:5,12,21
96:2 100:6 116:1	limitations 115:11	107:3 126:9 136:6	44:14 48:7 56:11	283:13 315:2,3
123:13,14 132:15	154:22	140:13 154:18,18	58:13 62:13 63:21	324:9,20 353:9,14
132:16 133:5	limited 34:7 44:21	166:10 196:4,7	65:7,11 69:14	355:14 358:2
135:15 138:19	109:12 204:7	209:8 222:9 232:8	74:5 96:12 102:15	375:22
139:4,6 140:9,15	217:13 252:3	243:14 254:10	130:6 131:7	looking 7:13 8:3,15
150:16 154:16	362:7 377:20	256:4 261:21	133:14 137:5,10	16:6 43:3 44:2
159:4 163:1,7,14	383:5	264:9,21 265:1	145:3 148:20	46:3 54:21 56:21
164:9 165:20	line 13:8,8 34:7,14	266:14 269:19	156:12 157:7	57:9,17 58:11
168:2 189:20	34:15 49:6 97:4	271:6,10 274:13	161:21 163:5	62:5,19 65:21
194:18 198:5	131:17 253:20	283:18 297:16,20	165:9,19,22	66:20 67:12 73:5
211:21 219:21	295:12 296:1	299:12,15 303:22	168:22 171:14	85:11 98:6 100:22
222:6 247:19,20	372:21	321:9 326:8,12	173:8 176:14	101:3 103:10,17
257:22 266:21	linear 205:11	347:11 349:11,16	178:3,7 179:17	107:21 112:18
267:20 268:11	lines 13:10 46:2,7	353:5,8,12,21	180:21 184:15	126:14 132:6
270:12 271:1	149:8,9 161:4	359:12 376:7	188:21 189:19	133:15 135:6
284:12 298:11	229:14 239:13	383:7 390:19	196:10 204:15	140:19 145:2,12
316:1,5 318:20	259:3 285:21	live 102:7 113:16	206:6 208:7,13,16	145:14,15 146:9
328:1,6 329:14,14	376:16 394:19	155:11	209:1 212:1,16	151:3,14 160:11
334:16 335:7,21	link 26:11,12 47:16	lively 141:2	215:21 217:12	165:8 188:19
336:9 342:3	279:20	living 295:2	220:20,22 221:5	189:10 200:17
343:14 344:15	linkage 74:5 250:7	local 194:18 388:4	224:13 230:19	202:16 203:18
346:22 347:14	250:11	locally 194:14	235:12 247:13	204:13 209:2,3
348:4 349:22	linked 40:11 72:22	location 146:6	249:22 251:16	210:22 223:16
378:13 383:3,20	73:6 224:5 306:7	log 31:9,16 114:4	253:3,9 254:13,19	233:18 248:16
388:8	316:11	114:14	255:1 266:17	253:5 258:9
leveling 156:5	linking 224:8 231:5	logged 157:12	273:4 274:17	265:16 268:20
levels 16:2 115:22	231:10	logic 30:4 35:1,3	276:18 282:2,7	291:17 303:18,20
201:6 208:12	list 98:6 99:6	294:11,17	296:18 297:3	315:10,11 317:10

317:13 318:4	370:17 371:16,17	222:14 223:1	mean 39:4 44:10	176:10
330:6 331:1 332:6	372:10 373:21	233:6 242:16	55:15,16 58:3	meaningful 178:8
332:7 333:3	378:9 382:7 384:2	257:13 359:4	66:11 74:22 80:21	205:9 342:16
354:16 359:21	384:16 385:4	397:3	81:10,22 97:15	means 7:15 36:3
369:14,19 372:1	387:15 391:15,18	manage 308:14	101:8 104:11	55:5 57:21 67:9
381:2,4 384:7	391:19,21	387:2	106:18 107:6,9,18	128:18 256:17
385:6 397:5,8,18	louder 84:10	management 70:11	107:19 110:5	366:14 382:8
looks 23:7 46:10,12	lousy 175:21 344:7	317:7,10	112:7 125:3	meant 86:17 195:9
122:13 145:22	love 17:20 207:13	Manager 2:19	132:12 133:9,10	297:21
162:12 181:21,22	269:3 300:10	managing 101:6	133:20 135:15,21	measurable 56:15
203:9 204:10	367:15 378:7	manner 310:12	135:22 136:20	195:22
251:22 253:4	loved 351:8	manpower 375:13	137:2,20 140:4	measure 4:9,10,11
275:18,19 288:13	low 28:14 56:9	manual 276:8	142:6,9,13,16	4:12,13,14,15,17
357:8,9	70:19 71:2 82:10	MARK 3:1	143:20 153:18	4:21,21 9:3,12
loosest 287:18	82:14,20 94:4,15	marker 54:16	155:14 162:21	14:5,9,11 16:14
lose 107:15 299:4	118:16 125:1	98:17 101:5 113:7	165:15 166:2	17:12 20:7 22:14
306:4 321:14	136:11,18 158:17	113:7	167:22 168:11,11	23:2,5,19 24:6,21
322:11	162:12 167:15	Mary 2:10 144:20	181:14 203:6	24:22 25:6 30:7,8
losing 342:13,17	170:12 180:11	188:14 207:20	204:15 205:12,12	44:15 45:16 47:12
loss 30:11	185:11 190:19	220:7 228:16	206:16 209:7	49:22 50:4,5,15
lost 78:6 190:14	191:8 201:12	231:18 239:7	215:1,7,12 219:2	51:8,21 57:7,11
274:13 343:20	228:9 236:7	252:16 255:9	220:2 222:1	58:4 60:14 63:14
lot 5:6 6:18,21	lower 45:6 148:1,6	343:10 392:6	226:20 239:16	63:19,22 64:5,16
17:14 23:21 25:19	170:22 172:21	Mary's 224:11	240:14 245:17	64:18 66:3,13,14
28:15 29:2,18	261:2 262:3	228:12	246:5,8,9 247:11	66:16 73:2,7,10
30:12 33:4 46:8	309:15 392:13	Mason 2:7	251:19 253:9	74:7,15,19 76:17
53:9,16 55:15	lowering 183:3	mass 102:21	265:18 286:1	76:19 77:2,15,18
65:16 66:3 71:18	luck 337:4	Massachusetts	288:12 289:1,5	79:4 82:12 83:6
72:3 78:13,14	lumping 189:2	261:14	294:15 298:16	84:1,4,14,20 85:1
80:22 83:4 85:19	lunch 264:2,9	master 229:12	302:13 303:16	85:5,5,20 86:8,14
91:13 101:8 107:7		masters 361:5	304:1 305:10	86:17,18 88:5,10
109:21 110:14,19	M	match 266:9	311:8 312:17	90:5,10 91:1,2,14
110:20 128:4	magic 280:2	matches 268:4	321:22 322:18	92:5 112:19 113:9
131:6,19 134:14	main 161:18	367:7	325:3 326:7 329:6	113:14,20 117:6
136:3,5 137:5	maintain 227:13	matching 321:17	332:17 333:4	117:20 118:4
142:21 144:5	maintained 256:12	material 281:16	340:4 349:16,18	120:5 122:5,12,12
145:13 159:11,18	maintenance 1:3	materials 263:20	349:21 352:2	122:20 124:11
172:4,8 188:22	226:11 233:16	matter 166:19	355:11 359:7	125:5 128:5 129:8
196:14,19 197:8	297:5 310:1 341:2	171:6 192:7 220:5	362:19 363:2	132:22 135:16,20
206:8 207:7	major 25:2 104:7	227:15 264:12	364:22 374:21	139:10 143:1,2,8
211:16 214:12,13	170:13 259:19	398:10	377:6 378:3	144:16 145:21
217:16 240:19	352:4 362:18	matters 107:4	385:13 386:7,17	146:14 147:7
250:5 254:17	majority 33:18,22	205:10	387:5,11,13 388:5	150:15,20 151:11
294:18 335:4	37:22 45:2 59:8	maturation 246:1	389:14 390:5	151:13,21 152:5
349:8,18 364:13	180:14 358:4	MBA 1:17,18 2:9	394:15	153:10 155:8
365:1 367:13	making 36:1	3:1,20	meaning 13:19	156:7 157:17
368:6 369:21,22	116:14 177:9	MDC 23:13	122:17 126:15	158:1,7 161:11

162:14 163:13	297:10,15,20	158:18 254:6	266:4,15 267:5,18	380:18,19 381:16
166:18 168:12,13	298:20,20 301:21	measures 2:14,15	269:17 270:10,13	382:22 383:10
169:22 173:15	301:22 303:11	2:18,20,22 4:4,20	270:17,21 271:1,3	390:6,16 393:11
178:1,9 183:19	305:14,19,20	5:16 6:1,7,17,18	271:11,15 272:6,8	393:11,14 395:21
184:22 189:7,9,16	308:21 311:15	7:8,12,16,22 8:3	272:10,22 273:13	396:5,10,15,16
189:21 190:7	312:7 314:3,6,21	8:18 9:13,13 10:5	273:21 274:1,3,4	397:11,15 398:2
193:2 195:20	318:17 319:10,14	12:12,16,22 13:5	274:8,21 275:8,10	measure's 209:16
198:7,20 200:13	321:15 322:1	13:12 15:20 16:9	275:12,14,17	measuring 159:3
201:8 203:12	325:14 326:4	16:11,12,15,15,20	276:1,2,7,22	162:13 184:2
204:1,6 205:15,16	327:21,22 328:2,8	17:8,12 18:2,6	277:8,13,18,19,22	215:17 274:7
206:6 208:2,10,22	329:12,13,21	20:1,1,3 21:15,22	278:2,6 279:4,14	285:5,6 321:15
209:3,6,19 210:15	330:7,11,19 331:2	25:1,3 26:10 30:9	281:20 282:5	333:19 338:13
210:18,18 211:1,2	332:1,6,9,9,19	39:2 43:19 51:17	283:4,19 284:6,19	339:4 347:17
211:4,11,15,19	334:14,19 335:13	57:18 62:22 63:10	285:4,8,9 286:3	387:6 393:3
212:17 214:14	335:20 336:4,7,9	63:12,15,17 66:6	286:14 288:21	meat 279:7
215:19 219:10	338:8,9,16 340:21	69:12 74:10 75:6	289:6,19 290:7,21	mechanism 8:10
221:22 224:18	341:1,1,3,22	75:12,15 76:13,15	291:1 296:10	16:16 21:3
226:7 227:11	342:1,1,2 343:9	77:5,7,10,21	297:8 298:5,8	med 330:4
228:15,22 232:9	345:11,14,19	80:10 84:12 85:3	302:3 303:9,17	median 125:21
232:10,18 233:8	347:5 351:9,19,21	105:20 118:3,5	304:8,13 305:3,11	Medicaid 126:16
233:16,17,19	352:22 353:16	124:20,21 131:20	309:22 310:7	medical 1:22,23,24
234:8,22 235:10	354:2,5,7,11,12	137:20 141:2	311:1 312:22	2:2,2,5,6,7 3:1,18
235:16 236:14,20	354:20 355:1,13	143:4 158:9 168:3	313:7,9,10,14	3:21 25:2 88:8,13
237:7 238:19	356:12 358:15,16	172:7 173:4	315:2,3,9,16,21	88:16,20,22 89:20
241:3 242:11	358:17,21,22	180:20 183:11,15	317:1 318:14,16	90:19 96:7,10
243:4,4,7 246:1	359:2 361:21	184:6 186:15	326:18 328:14	100:11 123:8
247:4 249:2,15	362:7,12 363:22	187:8 192:11	329:8,15 331:11	158:10 161:12
250:1,20 251:3,10	364:6,10 367:16	193:4,11,15,22	335:8,9,15,16	164:4,9,14,17
256:10,16,21,22	367:16 374:3,16	194:1,8,14,21	336:12,16 338:1	180:22 181:10
257:21 264:4	377:21 379:5,22	195:2,5,8,13	339:1 340:5	259:17
265:5,9,12,15	384:15,17 385:2,5	196:5,13,18	341:21 342:6,14	medically 320:10
266:2,3,12 267:10	386:5 387:1,4,5,7	197:12,19 198:16	342:17,18 343:8	Medicare 17:1
267:12,13 268:1	387:16,22 389:12	198:17 199:5,17	345:1 346:22	40:11 90:20 102:9
269:3 270:5,13,15	389:13,16,20	201:19 203:17	347:1,5 349:4,13	103:12 112:14
270:18 271:2,8,10	393:1 394:14	204:14 212:2,17	350:14,16 351:14	120:15,18 126:16
271:18,20 273:2,8	measured 9:20	215:15 224:21	352:13 353:13,16	147:17 151:2
274:17 275:5	227:6,15 238:10	225:19 229:6	353:22 355:4,21	302:3
276:11 277:2,4,7	327:22 392:20,21	233:3,11 237:3,10	356:15 357:8	medication 141:12
278:16 282:10,13	measurement 50:1	237:13,15 241:20	358:8,19 361:17	168:16 374:4
282:17 283:7	193:9,16 194:4	244:5 245:14	362:11 363:15	medications 139:22
284:10 285:18	196:22 209:5	247:1 248:8,9,13	364:3 368:3,12,16	322:7,10
286:6,11,18	216:13 221:9	250:2,18 251:9	369:7,10 370:12	medicine 2:4,9
288:13,18 289:3,8	222:13 231:6	252:7 253:19	373:2,3,22 374:5	24:11,12 252:22
289:14,15,19,20	254:8 255:6 256:9	257:17 260:1,3,9	374:11 375:7	261:8 327:3
289:22 290:3	261:9 342:4 378:2	260:18,20 262:9	376:3 378:5,6,10	medium 94:3
291:2,19 292:3,5	392:22 393:16	263:12,14 265:5,8	378:16,17,19,22	118:22 119:22
294:7 296:14	measurements	265:11,17,18,22	379:6,15 380:7,16	123:20 127:2,12

128:6 185:16 191:3 meet 6:8 101:13 118:3 240:3 270:5 325:11,22 351:8 meeting 5:5,6 22:19 35:17 265:7 325:11 369:17 394:18 395:10 397:19 meetings 64:15 meets 265:5 meets-the-road 176:16 member 4:18,22 18:12 19:10 20:18 22:3,8 23:1 24:8 25:15 26:8,20 27:15 28:12 31:2 31:14 32:8 33:8 36:15 37:13 38:8 38:14 46:1 47:4 48:1 49:2,21 50:13 51:12 52:1 52:4,6 53:3,21 54:12,19 56:17 57:13,16 58:6 59:14 60:18 61:1 61:14,22 66:10,20 67:5,8 68:10,17 69:1,11,21 70:22 71:17,18 72:6,19 73:12,17 77:14 79:1,13,17 80:1 80:15,20 81:16,21 82:13,22 83:9 89:21 92:4,14 94:1,3,18 101:17 102:1,11 104:3,13 104:16 106:4 109:2 111:12 112:11,13 113:3 114:2,8,16 118:19 119:18 121:5,10 122:11 123:18 124:22 125:19 127:11 128:1	129:5 132:10 133:9 139:11,20 144:21 146:5,22 147:9,14,16 149:11 150:14 151:8 152:1 153:17 156:10 159:15 160:12 162:6 163:16 167:13 169:7 173:18 174:4,12 175:18 177:21 178:11 179:15 180:8 182:12 185:14 188:6,12 188:15 190:3 191:1,11,13,16 200:1,16 201:16 202:5,9 203:6,21 205:4,19 206:13 206:16 207:3,15 207:21 209:15,21 210:12 212:5,15 215:7 216:6 218:3 219:1,18 220:9 221:19 223:4 224:10 226:20 228:17 229:16,20 231:3,15,20 233:13 234:15,20 235:7 236:11 238:5,20 239:7,14 239:20 241:18,19 243:17 245:13 246:3,12,17 247:9 248:2,21 249:6,21 250:5 252:17 255:10 256:4 257:5 258:1 268:18 279:11,17 280:3,7,17,22 281:8 285:12,17 285:22 288:10 289:18 290:14,19 290:20 294:10 296:6 297:13 298:15 300:4	301:11 302:13 303:20 305:2 306:19 308:19 309:11 311:6,19 312:12 318:1,6,10 318:13 320:5 321:2,5,19 322:14 323:7 324:1,7 326:19 328:15,20 329:3 330:21 331:7 332:14 333:14 334:8,21 336:19 338:4 343:5,11,16,21 344:2,4,6,14,20 346:12 347:16 348:12 351:7 352:1 355:11 356:20 357:22 359:6,20 362:19 364:9,19,22 366:2 366:17,20 368:15 369:5 370:4 372:22 374:8 376:22 378:20 380:6 381:9 382:20 383:22 385:12 386:1 387:3 389:16 390:5 391:8,21 392:7 393:6,19 members 28:3 30:20 31:1 55:20 56:1,7 64:4 91:15 91:17 93:14 94:2 120:8 127:12 128:9 319:8 membership 396:14 Memorial 1:21 3:8 24:17 memory 4:16 201:20 242:13 men 93:2 mental 179:17 180:2 mention 369:16	mentioned 16:16 152:12 173:22 183:19 184:8 249:9 merely 38:3 merits 212:1 message 337:11 met 1:9 371:1 method 15:13 21:17 90:11 91:6 261:1,4 262:2 347:21 361:4 methodologic 52:21 369:19 methodologies 261:11 289:2 methodologist 5:18 methodology 32:12 32:15 128:18 159:17 197:1 309:21 methods 6:20 12:13 102:14 197:6 261:20 262:5 298:18 370:1 metric 188:18 333:16,19 334:3 334:10 335:1 metrics 15:15 108:11 388:5 mg 327:12 MHA 3:21 MI 293:3,4 390:8 Michael 2:1 45:22 58:5 78:4 80:19 129:4 151:22 203:5 215:5 226:19 247:8 257:4 294:9 324:6 331:6 374:7 385:10 389:20 Michael's 49:3 213:22 389:12 391:2 Michigan 1:16 mid 396:13	mid-August 396:2 mid-September 397:18 migraine 378:17 mike 73:16 miles 388:21 million 206:19 220:10 261:14 mind 9:3 108:12 146:21 194:10 286:10 317:20 345:13 398:1 mine 129:1 203:6 229:18 234:16 minimize 75:18 76:3 minimum 365:16 minor 151:1 333:16 352:3 minority 59:9 132:13,19,21 133:21 minute 85:2 86:15 87:7 minutes 5:11 84:3 173:20 269:14 388:19 misabeled 284:2 misleading 57:22 misled 248:22 mismatch 367:15 missed 166:4 263:6 missing 23:15 124:5 125:13 161:19 223:17 245:3 250:9 260:14 262:19 mistaken 258:3,3 misunderstanding 248:1 249:4 misuse 48:4 57:9 64:4 73:22 74:4 74:14 misused 63:22 miswording 68:1 mix 85:17 132:6 156:3 187:15
--	---	---	--	---

mixed 232:3	10:15 11:3,21	morbidity 125:5	Motor 4:15	149:8,9 285:21
modality-specific	12:1,4,17 15:6	morning 5:3,9 6:5	move 7:20 32:15	mutually 140:7,7
248:8	19:15 21:5,9 22:1	7:5 15:20 16:7	70:20 83:21 92:2	myriad 141:9
model 10:14 14:2	29:15 36:21 37:5	24:9 31:2 65:1	115:16,19 122:4	M.A 1:13
14:10 15:12,14,17	39:16 40:20 42:1	85:18 192:20	182:10 185:8	M.D 1:14,15,16,17
19:17 20:14,20	42:6 48:17,20	250:3 259:12	192:14 226:17	1:18,19,20,21,23
22:12 29:22 30:14	61:3 72:4 78:15	270:8 276:12,17	243:11 252:19	1:25 2:1,5,6,9,11
30:17 35:11 36:3	79:14 88:16 89:19	295:1	258:12 273:22	2:13 3:2,5,8,12,13
36:4,10 39:18	91:12 97:1 101:3	mortalities 32:2,13	274:15 281:12	M.Ed 3:7
40:16,21 41:1	105:14,17,22	93:10 115:18	289:16 299:10,13	M.Sc 1:14
43:1,16 44:19	106:8 108:1,11,12	mortality 4:5,6 6:1	318:20 326:12	
45:2,9,12 46:22	108:21 110:9	13:4 16:21,22	380:21 382:11	N
47:1,10 48:14,19	111:9 115:4 116:3	23:3 25:2,4,5,5,20	392:15	name 176:6 192:21
51:21,22 52:9	117:15 128:15,16	26:14 29:13 30:8	moved 115:14	253:19 259:13
53:2,19 59:17	136:21 137:6	31:21 32:22 33:16	319:5	354:11
62:2,5,6 68:12	151:16 165:7	35:1 36:18 37:5	movement 173:13	narrow 41:4
75:3 78:6 80:10	167:2,3,4 176:5	38:18 42:11,12,22	moving 82:12	Nashville 172:12
85:15 88:8,10,12	260:6,6 263:4	42:22 43:6,15,19	118:18 119:17	national 1:1,9 2:11
88:14,21,22 89:1	293:22 299:14	44:2,15 45:5,6	124:10 125:18	14:1,2 88:22 89:9
89:17,20 91:7	300:11,15,19	46:20 58:21,22	192:10,16 237:7	89:12 102:9
95:14,19,22 96:4	301:7 307:18	59:18,21 63:16	248:19 329:15	126:17 158:19
96:6,7,10,11,12	309:18	64:20 65:8,11,14	377:14 384:9	181:7 193:9,16
96:15,20 98:7,19	moderate 25:18	65:19,21 66:12	MPH 2:7,19,21	194:3 204:21
99:4 103:1,3,22	26:2,6,22 27:11	67:4 69:14 72:17	3:19,21	216:13 221:22
105:3,6,11 106:6	28:10 43:8 70:19	73:5 74:6,15 75:4	MRI 6:13	222:12 262:12
106:18 107:4,18	82:10,20 91:22	75:9 79:3 80:17	MS-DRGs 36:4	342:15,19
107:20 108:3,4,16	93:20 94:10,15	81:19 84:14 85:5	muddiness 331:3	nationwide 193:8
108:17 112:20	118:16 119:15	85:6,6 86:4 90:4,7	Mullen 3:17 192:20	natural 220:1,5
128:21 133:6	121:1 124:9 127:8	90:17 93:5,9 94:8	192:21 202:4,6	242:6
134:10,21 136:3	127:20 185:10	96:19,22 104:6,8	209:20 210:1	naturally 220:18
138:22 139:2	190:19 191:8	104:19,21 113:8	216:10 217:6	nature 70:6 171:2
140:18,18 142:2,7	228:9 236:7	113:11 115:5,8,22	222:3,21 225:6	near 50:22 74:14
142:10,14 160:4	modification 59:12	116:1 120:2,16,18	236:22 251:10	348:9 349:4
160:14,21 161:5	modified 7:1	125:5 139:6 161:6	258:22	nearly 40:19 384:4
161:12 162:18	modify 72:3	178:4 261:2,3,10	multifactorial	necessarily 113:19
164:10,15,15,18	moment 211:2	262:1,3,22 274:5	159:1	135:2 176:9,10
166:7 167:3	281:12 345:7	274:7 276:11	multiple 16:20	204:20 255:17
168:22 170:9	351:6	283:19 284:18	58:11 158:8	284:21 306:22
177:16 178:7	Monarch 71:10	285:3,5,6 286:1,2	183:15 244:6	312:16 338:10
180:1,6 260:16	money 45:15,18	286:7 292:19	266:4 272:8	351:13 371:5
291:22 294:6	74:11 372:11	294:4,5 295:18	276:21 277:18,22	necessary 34:10
302:8 311:17,20	377:20	300:18 301:2	278:2 286:14	315:16 359:2
312:4,8 313:12	Montefiore 2:2	305:20 307:19	314:5 340:3	need 10:7 11:13
314:12	months 85:13	308:17 310:5	multiplied 371:12	15:3 26:9,11
modeling 14:8 30:9	90:21 98:12 112:9	311:8,10 313:7,19	multitude 174:22	86:22 87:17 92:7
85:16 191:15	129:21 148:14	314:3	multi-way 309:3	100:21 107:21
models 8:15 9:16	159:12 385:18,18	motivated 149:2	mute 13:8 139:17	118:8 119:2

123:10 124:12 149:15 160:21 181:19 183:21 186:3,8 189:1,18 210:13 220:4 234:18 240:15 247:4,9 249:2,22 255:1 256:14 260:9 264:17 268:10,17 274:8 280:3,8,20 291:22 301:7 305:5 316:7 324:21 325:1 328:13 334:4,5 340:8 344:1 356:9 357:19 363:21 370:1 376:6 386:21 392:10 394:17 396:9,10 397:1 needed 16:20 185:19 263:10 340:16 359:18 needs 175:14 283:18 307:4 346:10 369:22 negative 66:17 neighborhood 217:7 neither 140:7 304:9 Nemours 2:6 Net 79:7 Network 64:16 Neurogenic 239:9 neurointensivist 109:9 neurologic 259:22 neurological 397:5 neurologist 2:5 109:10,11 189:15 303:8 388:11 neurologists 86:7 255:11 259:18 327:2 345:19 Neurology 1:3 3:19 55:18 259:14 309:17	neuroscience 24:19 259:19 neurosurgeon 109:10 neurosurgeons 58:20 never 139:8 146:21 183:19 195:3 367:3,3 384:13 390:2 new 1:13 3:2,5,10 3:13,15 51:2 83:13 96:6 159:10 172:8 261:7 265:8 270:10 284:15,15 284:16 289:3 310:9 326:4 350:12 351:18 353:7 361:1 371:13 377:6 382:6 396:11 newly 129:12 nice 5:21 85:17 219:12,13 nicely 161:7 nidus 153:9 night 201:18 283:12,14 284:18 352:13 NIH 6:14 18:15 39:22 40:13,20 96:2 178:19 226:22 326:21 NIHSS 262:12 263:2 nine 58:20 82:9 192:1 nineteen 125:16 nobody's 247:16 372:22 nodding 39:7,10 noise 27:21 134:11 134:15,16 NOMS 218:10 non 139:21 386:9 non-acute 314:1 non-EMTALA	38:3 non-endorsement 290:16 non-FT 293:3 non-hierarchical 12:3 non-motor 373:17 373:18 non-stroke 355:6 Norbert 3:8 35:7 53:8 normal 223:11 normalization 81:14 normally 335:10 norms 184:21 north 1:25 216:21 Northwestern 2:8 nos 83:2 note 10:15 15:18 92:20 93:1 194:8 195:19 noted 68:18 126:1 185:21 191:13 204:2 376:4 notes 10:10,11 109:6 110:8,9,13 nother 334:5 notice 377:17 390:1 noticed 10:9 13:14 201:18 281:15 noting 126:8 233:4 310:4 novo 96:4 NQF 2:13 4:3,18 4:22 5:16 7:9 8:5 8:17 9:3 11:6 12:7 16:11 21:2 21:20 41:14 63:11 63:20 74:22 75:6 75:18 76:11 77:1 117:5 120:7 157:17 185:5 192:14 193:21 194:11 196:6 197:22 203:22 206:3 218:9 225:8	225:8 226:9 237:6 240:16 251:3 260:3 265:3 270:5 289:6 349:1 351:17 354:10 371:21 374:9 375:6,9 377:3 380:18,22 381:12 390:6 395:14 396:14 NQF's 117:10 240:3 NQF-based 242:18 NQF-endorsed 25:3 NTIA 360:16 nuance 152:18 number 18:8 27:6 31:4,22 47:9 74:18 78:7 90:12 100:11 109:14 128:8 136:20 137:7 146:8 153:22 156:14,15 162:16,17 165:6 171:16 184:18,20 189:12 210:16 211:6 212:11 213:15 216:19 223:8 229:22 239:15 248:10 259:6 275:4 283:16 309:12 314:21 320:21 342:7 371:4,10 372:17 374:5 384:3 387:8,16 394:22 numbers 11:20 81:2,8,9 199:8 200:17 204:14,16 205:1 206:5 207:1 210:14 212:8 214:11 216:11 217:12,14,21 227:22 235:3 260:3 324:14	354:10 numerator 29:12 47:21 201:4 205:6 235:12 284:7 360:15 374:21 numerators 266:8 nurse 24:19 nursing 44:13 111:15 115:9 142:8 146:7 177:8 NW 1:10 <hr/> O <hr/> objected 372:4 objection 44:11 objective 255:6 obscure 10:15 observation 190:5 observations 11:14 13:19 91:11 observed 42:11 67:2 93:10 311:10 obvious 129:14 385:5 obviously 6:16 15:13 18:17 40:1 52:15 53:14 65:22 73:3 118:4,9 130:2,18 157:16 194:10 201:8 216:1 271:12 272:12 276:6 282:3 289:5 294:19 302:2 305:21 313:12 314:11 328:6,9 342:20 379:5 occasionally 9:16 10:4,21 12:3 occur 50:19 170:21 306:16 309:12 314:7 occurred 26:1 123:12 occurrence 16:5 occurs 305:16 October 397:20
--	--	--	---	---

odds 31:9,17,19 114:4,10,14,20	234:4,7,13 245:11 253:13 254:19 256:2 257:3 258:19 259:9 263:22 264:15 265:3 266:5 269:13 272:20 273:9,18 279:5 281:8,19 282:14 283:10,20 284:4 285:8,19 290:19 291:13,15 299:7 312:12 313:1,2 314:20 315:1 318:10,10 319:5 325:12 327:18,20 348:12 350:2 351:12 352:7 353:7,10 355:6,18 355:19 357:5,13 358:15,17 360:5,7 361:7 362:12 363:11,18 367:21 381:8 384:11 392:5 394:12,17 395:6 398:4	ongoing 285:18 online 279:19 395:17 open 93:17 94:13 118:13 119:10 120:21 121:20 124:1,15 127:5,16 190:17 191:6,22 202:21 228:6 233:6 236:4 250:19 251:2 259:2 279:8 364:4 378:6 394:17,19 opening 302:21 operated 46:9 operational 120:5 operationalize 181:3 operationally 212:6 operator 18:7,10 149:9 259:2,4 285:20 394:19,20 394:21 opinion 55:21 205:20 222:2 317:15 332:22 opinions 309:7 357:19 opportunities 70:2 166:4 171:16 274:17 295:19 297:1 345:9 347:7 opportunity 26:21 36:12 55:20 59:20 65:16 164:4,21 169:8 177:2 180:17 198:14 204:5,12 206:7 259:15 263:6 275:3 340:15 395:20 opposed 6:19 55:3 55:6 56:14 74:12 110:7 113:1,6 182:15 276:4 345:6 391:2	opposes 260:17 opposite 382:10 opposition 262:8 263:18 opted 361:13 optimal 346:6 options 312:2 oranges 329:5 order 24:5 48:13 52:16,16 87:11 95:13 130:9 163:2 181:18 186:3 192:15 234:10 258:6 259:5 283:17 313:11 323:14,16 342:21 362:21 363:11,20 374:2 394:21 ordered 253:13 254:18 315:5 362:14,22 363:4 ordering 253:12 orderly 207:19 orders 54:14 363:8 ordinal 195:18,19 organ 30:11 organization 69:13 75:22 organize 57:2 376:8 organized 381:12 orient 315:1 origin 149:22 307:16 original 31:4 49:9 162:7 308:14 375:21 originally 83:1 103:1 305:18 other's 221:5 ought 365:19 390:4 outcome 6:18 7:8 9:12,20 10:4 15:5 16:6 17:5 18:1 19:19 20:1 23:4 26:13,13 40:2 47:19 50:17 56:19	56:21 57:6,11,18 69:12,17 70:4 71:8 86:5 87:8 92:5 93:8 107:10 113:8,14 122:13 124:11,18,21 125:6,9 129:16 167:10 168:6 178:1 182:22 183:4,11,19 184:6 184:21 187:1 197:12,17 204:1 204:13 208:14 214:8 219:10 220:21 221:7 224:5,8 225:19 228:20 230:13 231:6 232:9,17 236:16 238:4,19 240:11 241:2,5 244:16 246:5,7,10 246:18 247:1,3,7 248:9 249:2 250:2 250:8,17 253:16 254:14 257:17,21 260:2 262:9 263:12,14 294:8 306:5 369:9,15 373:3 383:10,20 385:1 389:11 outcomes 3:3,6,10 3:14,15 10:12 63:18 73:8 84:8 86:22 87:1,5 91:2 92:19 126:2 139:7 143:2 170:1,4 183:17 184:3 186:14 193:9,16 194:3 209:3,6 216:13 220:20 222:13 231:11 240:8,17,18 241:11 243:5,9 244:2,8,11 252:20 253:22 258:9 262:10,17 293:5 295:20 314:14
--	--	---	--	--

369:21 382:4	225:12 227:20	Parkinson's 373:18	partly 107:10,12	109:16,19 110:10
outcome-based	230:11 232:12	397:9	150:19 368:2	110:19 113:16
381:16	237:19 238:18,21	Parkwest 2:5	Partnership 76:17	116:10 117:15
outgoing 297:4	240:13 241:15	parse 131:21 134:4	77:5 118:5	123:5 133:15
outlier 72:2	243:22 244:20	240:21	partway 142:12	134:19 135:18
outliers 187:13	245:1,4 246:20	part 20:6 22:11	pass 348:10 365:2	136:2,6 137:1,4
188:2,3	264:5 273:14	30:15 35:4 39:12	passed 283:12	137:22 138:13,21
outlook 286:12	274:14 276:14	44:17 66:5 112:5	passive 377:4	139:13,14,21
outpatient 85:12	280:12 283:3	115:19 120:6	password 280:4,8	140:16,19,21
112:8 323:15	286:15 289:5	121:15 130:7	280:20 281:7	141:3,3,21 144:8
344:16	296:21 298:10	142:15 158:1	Pat 3:22 24:18	144:13 145:15
output 95:19,22	304:5 312:16	184:14 197:2	33:17 65:4	148:10,17,19
outside 86:9,13	314:16 319:20	212:11 269:20	path 17:11 172:3	151:17 158:13,14
117:2 139:18	329:9 334:12	324:8,12 332:4	173:2	162:19 163:6
165:22 379:7	335:3 336:5	345:20 360:9	pathologist 208:1	165:10,11,12
outweigh 279:5	352:17 353:1	369:5,7 377:13	223:16	166:19,22 170:3
outweighs 278:2	357:2 376:11	379:11 381:13	pathologists 207:12	171:8,21 174:7
overall 92:21 121:3	380:13	389:18 391:22	208:15 216:16	175:6 176:20
121:21 145:9	pack 177:4	PARTICIPANT	224:20 232:4	177:4,9 178:21
156:18 157:5	page 9:6 23:22	291:6,13 292:6	pathology 193:13	179:1 181:21
191:10,11 294:8	102:14 130:19	313:14	194:22 195:11,16	195:4,6,8 198:5
322:18 379:2	159:17 230:20	participate 216:17	209:7 210:5,20	208:8,9 209:9
393:15	283:21 284:1	374:3	216:20 229:11	211:9 232:20
overarching 203:7	352:15,20,21	participating 5:4	230:5 231:10	244:9 266:20
214:20	353:4	347:4,12	233:5 239:2,18	268:20 270:15
overlap 326:3	pages 284:3	participation	241:10 243:8	277:10 284:10
oversimplified	pain 355:12	225:10	244:16 255:2	292:20 293:8
153:21	palliative 54:22	particular 19:19	369:7 375:7	305:17 312:5
oversimplify	56:3 368:16,21	36:8 46:22 65:2	pathophysiologic...	313:18,21,22
153:19 155:14	369:1	88:1 129:8 183:22	293:4	314:5 315:22
overstating 154:7	Palm 1:21	184:18,19,21,22	pathophysiology	316:5,22 317:8,10
overview 5:22 90:1	panel 29:5 89:22	184:22 203:15	337:7	320:2 339:10
ownership 27:5	120:8 232:2 292:4	204:17 205:2	pathway 155:15	341:6 346:22
owns 32:12	341:17 361:15	206:6 211:11	pathways 339:21	348:1,4 362:5,22
	362:4 391:7	213:5 214:8	patient 19:5 33:10	365:4,19 366:14
	panels 62:15	218:16 242:8,13	35:13 36:6,7	369:20
P	292:16	244:16 248:14	37:10 39:20 41:16	patients 11:15
Pace 2:17 5:15 7:5	panel's 126:22	262:7 288:8	44:5 46:20 52:18	13:20 17:1,2
13:11 18:21 19:14	340:20	289:15 290:3	53:5 54:2,17	23:11 32:21 33:1
21:1 22:6,10	paper 12:21 40:17	338:22	55:19,21 56:5	33:4,7,19 34:3
62:14 63:2,6	278:17 296:18	particularly 11:20	59:13 63:17 72:9	36:5 37:1,2,14
108:8 117:11	papers 300:21	62:11,12 137:1	72:13,14 85:11	38:17 39:14,21
124:17 125:7	paper-based 277:5	158:17 165:14	86:3,13,21 87:4,8	44:13 46:8 47:9
183:7 204:9	paradoxical 101:11	214:22 269:11	88:2,18 89:10,18	47:17,21 48:11
205:13 206:2,15	paradoxically	313:17 345:19	95:7 96:1 99:12	49:15,16 50:22
210:21 212:10	100:12 102:18	378:4 380:7 385:3	101:1,18 102:4,5	52:7 53:15 62:6
213:4 214:16,19	parallel 340:8	particulars 177:16	107:17 108:13,21	70:11 77:22 78:3
216:4 218:21				

78:8 79:9 80:11 80:12,13 82:3 85:14 86:1,9 87:1 87:10,19,21 90:6 90:13,16,19 91:9 92:22 100:7 102:7 103:12 105:16 110:6 111:6 112:15 113:8,15 115:2,8 116:18 117:1,13 122:15 122:21,22 123:2,7 123:9 125:22 126:12,14,15,19 131:15 136:5 137:14,16,17 141:8 145:22 146:15 148:5 150:3 153:2 154:9 154:13,15 158:17 162:17 163:13 170:20 172:21 173:3 184:1 188:22 189:17 190:4,8 194:18 195:2,17,22 201:20 202:11 203:13 204:3 205:1 206:17 207:7,8 208:4 209:16 210:7,14 210:19,19 211:6 212:8 213:7,11 214:2,5,22 215:22 216:20 217:3 219:3,9 221:7 222:6,7,9 225:2 239:5 241:8 255:13 257:1 262:10 275:18 285:7 293:6,15 294:11 295:21 298:21 299:3 302:8,10,19 304:10 306:2,3 308:3,7,11 310:2 311:21 313:17	318:18,21 320:16 322:17 323:3 325:11 327:4,12 327:15 328:17 333:20 337:20 339:11 341:8,14 346:20 347:19 356:6 359:21 360:1 365:9 368:6 370:13,18,22 371:1,11,17,20 372:8 385:14 387:8,14,16 patient's 33:12 86:4 107:10 131:10 135:13 149:19 175:2 195:11 patient-centered 138:8 259:21 260:11 patient-level 14:3 91:5 139:1,2 160:5,13,19 162:20 164:13 187:7 199:1 patient-specific 45:20 Patrick 3:18 24:10 53:13,20 60:12 61:6 295:9 307:15 Patrick's 77:6 pattern 53:12,16 paucity 178:16 pay 38:4,7 payers 75:20 paying 323:19 payment 76:16,20 118:7 220:15 241:8 pay-for 76:20 pay-for-perform... 392:17 PCPI 330:11 332:12 336:12 345:8,14 346:2 354:20	peculiar 306:11 pediatric 217:20 302:19,20 303:7 peer-reviewed 12:19 183:1 penalize 263:17 penalized 59:7 penalizing 50:9 penalties 115:20 penalty 392:13 Pennsylvania 2:4 people 7:15 35:3,19 40:3 46:14 54:22 56:11 59:1 66:18 89:7 98:3 100:17 100:20 110:14 116:15 119:22 121:6 128:6,22 129:9,22 130:2,3 131:19 137:19 138:13 139:17 149:7 151:10 153:22 161:21 166:8 171:11,17 171:19,22 172:14 173:12 179:8 182:2 194:6 204:16 206:5,8 211:16 212:19 213:5,9 214:12,13 217:14,17 219:19 223:8,9,20 224:1 226:6,10 227:6,17 227:22 230:22 231:7 235:2,8,14 235:20 247:21 248:11 251:3 253:1 295:1 303:6 312:21 316:4 320:17 322:20 324:14,22 349:20 349:21 350:16 363:7,9 377:4,9 377:10,12 378:5 384:1 386:4 392:20 395:19 people's 131:5	167:3 397:3 percent 25:20 43:14 44:21 126:1 126:3,4 200:20 203:14 206:22 207:8,9 212:21 214:1 216:15,22 217:2 219:3,8 221:7 223:19 224:16,19 235:19 242:16 247:2 255:4 316:11 320:7 324:12,15 324:15,18 326:3 327:16 330:22 343:22 368:22 370:13 371:7,7,8 371:12,18 380:10 percentage 23:8 48:18 162:17 223:20 225:1,2 318:17 320:16 371:20 percentages 324:13 percentiles 126:5 percolating 144:4 perfect 57:8 88:17 142:2,7 151:13 178:7 perfectly 205:11 370:9 perform 40:19 performance 2:14 2:15,18,20,22 5:16 8:18 11:16 12:22 15:15 26:21 41:3 45:10 57:7 76:21 92:15 93:13 93:16 108:11,16 125:18,20 127:1,4 198:15 206:9 208:12 211:15 212:2 277:12 324:10,11 330:19 334:15 344:22 350:18 performed 41:12	performing 15:17 44:14 107:19 343:18 period 175:13 259:12 261:15 308:9 351:5 396:1 periods 381:19 pernicious 64:1 persistent 80:12 person 36:7 95:3 118:21,22,22 119:21 120:5 121:6,11,12 123:20 127:2 128:5 185:21 210:1,2,3 220:16 224:6 251:22 310:18 personally 129:21 240:7 258:15 persons 123:20 127:1 person's 373:9 perspective 4:3 7:9 11:7 65:20 106:17 108:20 131:11 134:8 151:20 196:6 288:8 292:17 337:15 PEs 358:6 phase 264:18 275:9 275:10 374:9 378:15 396:21 397:1 philosophical 252:21 phone 24:15 35:16 139:17 149:8 168:9 177:11 181:6 343:3 physical 369:8 physician 53:22 56:5 72:12 84:7 109:9 111:19 177:8 334:1,2,4 336:2,8,9 338:8 338:15 341:10
--	---	---	---	---

343:14,18,19	139:4,6 140:16	317:18 323:21	poses 37:3	342:15 345:17
344:15 347:14	150:17 156:5	325:6 326:14	position 152:21	347:4,13,15,19
348:3 356:21	350:4	327:1 332:4,20	153:10	practical 12:6 73:4
374:2 393:8	please 13:8,9 25:14	338:5,10 346:9	positive 64:12	practice 44:12
physicians 53:15	35:16 61:2 123:19	351:2 356:9	366:13 369:10	53:12,16 64:12
56:3 109:18	139:17 149:8	372:15 378:15	possibility 44:7	109:20 111:20,22
111:21,21 112:4	187:4 218:14	380:18 387:4	222:5 288:11	156:11 195:2
112:10 339:7	228:7 276:20	391:2	307:13 332:12	208:18 225:4
344:10 345:17	280:17 350:13	pointed 37:21	336:13 357:17	230:3 238:14
386:13 388:9	364:7 378:19	322:7 346:15	possible 16:13	239:11 322:20
physiologic 40:13	397:12	378:8	72:22 73:9 265:19	327:2,3 338:14
physiological 30:10	plenty 48:6	pointing 105:7	266:1 272:16	347:3,3 360:3
Ph.D 2:1,3,17 3:10	PLL 2:5	166:20	274:2,10 301:6	practices 44:8 58:1
3:17,22	plots 62:18	points 170:14	305:21 308:20	64:1 77:21 232:19
pick 147:21 148:7,9	plug 378:14	175:20 176:14	317:11,20 336:14	393:8,9
148:18 267:9	plus 98:12 217:3	182:13 183:8,9	360:21 368:14	practicing 368:5
297:16	pneumonia 25:4	233:14 236:20	post 141:14 152:22	practitioners
picking 29:8,13	39:10 145:19	318:19 372:18	395:16	255:12
picks 148:5	171:22 293:11,12	377:17	post-acute 158:16	practitioner-based
picture 138:18	295:13	point's 295:11	168:20	297:15
piece 103:21 245:2	POA 99:5	Policy 3:23	post-discharge	pre 384:17,20
260:15 296:18	point 11:1,7 34:16	poor 98:15 106:8,9	123:10 152:8,13	386:18
307:6	36:2 38:15 49:3	106:11 159:19,22	154:15 155:18	precautions 175:8
pieces 105:11 249:9	53:10 54:6 57:22	160:3,22 163:18	post-hospital	precisely 73:2
pilot 351:18 376:18	58:7 61:21 69:4	164:19 186:7	385:13	197:18
piloting 376:13	78:5 80:21,22	392:21	post-score 195:14	predict 87:7 135:12
pipeline 378:16	81:12 82:6 93:11	poorly 58:2 339:13	potential 17:11	161:9 162:18
place 120:4 148:6,8	106:5 130:12	339:15	48:4 167:21	163:12 171:2
148:9,15 151:4	133:1 140:13	population 17:6	175:16 194:12	173:6 187:7
153:3 231:1 281:1	152:2 158:8	59:3 65:10 93:8	206:4 218:8 227:4	predicted 67:2
298:3 342:13	160:20 165:5	120:18 126:7,7	227:17 300:2	96:19 104:6
368:6	177:22 187:16,17	265:10,13 266:20	360:16 394:14	185:18
placebo-controlled	200:1 201:16	270:14,16 271:3	potentially 44:6	predicting 40:2
221:20	205:7,9,10 206:14	273:3 277:10	49:11 72:22 75:7	106:8,12 136:15
places 144:5 296:1	213:22 214:18	284:10 289:8	116:4 166:1 248:5	166:3 268:10
plan 195:12	217:11 219:21	297:22 299:1	256:8 270:9 295:5	prediction 88:18
planned 129:18	231:4,18 234:22	302:18 312:5	333:3,4 345:10	100:13 101:15
130:11 276:4	239:22 240:1	328:8 330:8 355:7	346:2 365:18	163:6 262:22
plans 158:14	241:21 242:3	356:7 359:3 362:5	372:16 375:9	predictive 106:9
226:15 324:3	246:21 247:12,13	populations 10:16	393:10	186:22 262:14
350:17	251:2 252:6 254:2	126:10 151:17	power 45:3 48:19	predictor 68:12,13
plate 129:21	256:13 262:6	270:19 306:11	60:8 101:15	68:15 91:3 161:17
play 104:5 105:20	269:9 272:15	332:10	262:14 299:11	162:3 262:9
139:14 159:2	292:6 295:17	population-speci...	PowerPoint 64:22	300:16
170:3 368:13	296:20 298:15	303:5	394:4,6	predictors 137:2
373:14	301:16 304:12	posed 23:20 28:15	PowerPoints 65:2	predicts 162:1
playing 138:19	307:16 313:9	31:3 94:22 128:9	PQRS 199:19	prefer 10:13 16:12

275:20,22 287:4 287:22 288:6 293:13 preference 54:1,2,9 54:9 183:11 260:11 275:14 289:6 preferences 53:17 278:20 pregnancy 103:13 306:10,12 pregnancy/child... 23:14 preliminary 121:11 191:13,14 365:12 Premier 71:12 172:11 prepared 384:7 preparedness 390:14 prescribed 315:5 prescribing 323:18 prescription 385:15,16 prescriptions 323:19 presence 121:14 368:20 present 1:12 3:1,24 10:1 15:7 31:16 32:7 37:7 56:18 61:3 62:8 67:21 68:3 80:11,12,13 98:9 99:8,10 108:14 165:13 200:14 237:22 243:19 244:3 296:7 384:8 presentation 60:2 255:22 292:21 293:14 294:16 295:13,14 presentations 9:5 presented 92:16 114:5,18,19 125:20 164:1 181:4,5 212:22	218:7 229:18 230:2,12 234:14 236:12 245:6 383:6 394:4 presenting 31:9 62:3 122:10 213:9 presently 336:1 PRESENT(Cont'... 2:1 present-on 39:4 68:5 present-on-admi... 39:3 68:7,9,16,21 president 2:13 150:7 presidents 13:1 128:13,16 presiding 1:11 press 18:8 258:17 259:6 394:22 pressed 354:18 pressure 100:22 presumably 81:4 pretty 18:17 61:15 75:22 109:7 132:9 148:22 152:4 163:2 182:8 203:11 217:21 236:17 266:5 275:2 301:11 311:5 315:22 356:11,15 362:15 380:8 prevent 87:22 preventable 170:22 prevented 375:12 preventing 358:6 prevention 317:14 337:8 previous 62:15 98:12 112:9 236:21 237:7 306:20 previously 63:12 194:2 pre-hospital 386:2 386:18 390:7,8	391:14 pre-review 375:8 376:12 pre-score 195:14 primarily 7:7 193:7 194:20 primary 8:20 130:22 179:3 195:20 294:8 prime 244:3 principal 23:9,16 90:9 principle 116:11 331:9 364:15 principles 41:14 printing 284:15 printout 67:9 prior 85:13 86:9 90:21 121:15 200:3 private 111:22 156:10 322:20 327:2,2 probabilities 31:16 31:19 114:19 probably 19:7 25:13 40:11 45:17 49:22 54:5 105:12 111:19 113:11 132:11,18 133:20 142:15 147:10 148:15 151:21 157:18 159:4 179:20 181:16 186:17 198:13 199:15 222:16 244:10 248:7 268:17 280:9 281:11 287:20 298:1,11 313:4 316:14 317:18 326:6,22 328:6 330:18 346:17 355:17 359:18 363:9 376:4 problem 73:4 133:20 203:13	207:4,6 212:12 215:11 219:5,6 331:18 335:3 366:21 376:17 388:3 389:17 problems 48:5 156:19 173:11 213:3 219:10 242:18 346:9 procedure 42:4,10 procedures 41:12 130:15 208:3,13 238:11,13 procedure-based 42:7 proceed 236:10 252:8 process 6:19 7:12 17:16 20:1 26:10 26:10,12 35:5 70:8 76:12,15 143:4 148:14 164:6 170:6 183:15 191:15 209:11 228:20 231:5 232:10 233:3,11 237:11 240:9,22 244:5 246:7 248:16 250:1,7 252:6 253:18 254:13 282:4 293:18,19 294:20 297:10 324:22 331:8,9 348:14,20 349:15 349:15 350:8 351:19 368:10 369:12 373:3 375:5,8 376:7 377:1 381:12 393:16,22 394:11 395:13 397:17 processes 183:16 230:15 240:19 244:7 268:12 333:20 376:13 produce 88:6	291:21 produced 263:2 productive 64:7 profession 239:18 professional 54:9 239:8 professionals 259:19 professor 24:11 profile 86:19 96:9 profiling 88:4 profit 386:10 prognostic 87:4 prognostication 88:3 89:11 program 65:7 90:21 345:20 programs 50:10 77:8 118:6,7 260:19 342:15,19 progress 195:21 196:1,21 201:1 222:6,11,14,18 223:1 224:3 233:6 242:16 258:13 progressed 83:20 progression 242:6 project 2:19,21 166:2 281:22 282:6,11,12,21 283:5 353:14 356:2,14 358:22 395:7 396:21 projects 282:1 323:13 377:13,15 proof 73:22 74:1 proper 55:13 properly 50:7 prophylaxis 267:19 353:1 354:4,12 357:11 358:4 proportion 23:7 126:14 proportions 126:18 proposal 301:13 proposing 165:18 proprietary 30:4
---	--	---	--	---

278:20	259:16 260:18,21	putting 38:17	46:3 51:13,14	16:18 17:3 18:5
prospective 133:13	260:22 390:12	65:20 169:16	52:7 55:14 56:6	22:17 23:21 24:1
protective 100:12	394:18,20 395:18	256:16 272:9	60:22 62:3 68:5	25:13 26:3,16
102:18 104:19,21	publication 261:5	P-R-O-C-E-E-D...	69:18 95:6 98:4	27:8 28:3,7,15
300:18 301:2	262:21	5:1	99:18 102:3	29:19 30:15,21
protects 82:2	publicize 378:19	p.m 264:13,14	112:14,16,22	31:3 57:10 60:16
protocol 389:9	publicly 36:19 71:5	398:11	113:5 114:3 117:4	63:5 71:18,22
protocols 237:6	77:15 172:6		119:3 131:4,22	80:19 82:17 83:5
prove 166:11	238:17 276:3	Q	134:6 144:22	83:12 91:19 92:8
provide 15:16	published 40:17	QIs 310:17	145:21 146:4	93:16 94:12,21
22:15 32:13 36:10	55:18 108:2 183:1	quagmire 337:1	151:1 155:9,15	98:3,21 114:3,22
61:19 62:17	361:19	386:3 388:13	156:2 162:8	117:22 118:8
183:13 185:20	pull 65:15 79:10	quality 1:1,9,13 3:5	173:19,20 179:16	119:2,9 120:11
197:2 208:3	147:5 203:1 252:6	9:21 18:18 24:14	182:7 186:1 188:7	121:19 123:22
225:21 234:1	283:14 323:8	50:15 51:1 53:1	188:16 190:4	124:13 127:4,15
250:7 253:6 254:1	pulled 79:3	56:9 57:2 63:13	199:7,16 202:21	128:4,8,11,20,22
281:7 310:10	pulm 110:16	65:12,13 71:10	203:8 204:18	143:22 185:7
361:9 365:15	pulmonary 110:17	74:16 86:21 87:13	205:17 211:3,5,13	188:14 191:21
provided 29:2,11	140:1	98:15 108:18	215:9 216:5	196:14,17,17,18
66:21 108:18	punches 391:17	113:9 116:13	218:22 220:10,15	196:19 198:10
116:12 153:2	purchasing 115:15	143:3,12 148:21	221:15 225:16	199:11 200:2,6
180:12 198:7	purely 294:15	157:7 158:16	226:12 227:9,21	201:13 202:8
200:19 208:7,20	purpose 189:9	176:11 179:11	231:1,21 237:20	221:12 225:13
227:10 230:20	227:3 238:8	181:7 182:1	259:6 266:19	226:16 229:2
253:21 255:16	308:10 324:21	189:14,18 194:19	279:18 281:14	236:19 259:8
provider 42:6 54:8	purposefully 116:9	197:13 205:16	287:9 290:8 292:1	279:8 283:9 343:2
70:9 115:17,18	purposely 108:13	208:19 211:7	296:22 298:5,9	384:3 395:2 398:3
179:3 232:21	170:15 280:6	214:21 241:1	301:10,15 303:3	quick 5:12 6:7 7:21
providers 28:2	purposes 64:7	259:20 260:9	303:19 304:18	84:20 85:1 106:21
144:10 150:17	194:6	263:14,16 342:21	310:14 311:7	116:9 168:21
318:21 345:2	push 184:3 381:4	364:7,10 367:1,13	312:19 315:13	179:15 187:3
386:18	put 19:3 20:13 51:9	367:14,16,18	316:21 319:7	190:3
providing 59:7	54:3 106:17	368:3,9 373:15,15	320:5,6 324:17	quickly 12:12 18:5
141:14 259:20	113:20 139:5	376:15 386:5	325:2 328:11	19:11 61:8 281:6
proving 279:21	154:21 158:4,6	392:11,12,16	329:9,10,18 330:1	quintiles 93:6
provision 221:5	159:9 166:6	393:1,3,12,18	331:15 334:13,16	quite 23:18 31:17
proxies 42:14	198:11 214:15	quantity 197:13	335:18 341:20	54:6 62:1 64:9
proxy 80:10 124:18	215:13 216:10	241:1 368:9	345:7 348:14,20	80:1,16 88:15
125:8 230:17	217:6,22 230:11	quarter 23:16	354:14 355:22	89:16 91:13 94:18
psychiatric 104:7	240:8 242:14	200:21	357:3 359:1,17	101:13 128:4
PT 2:8	245:8 253:19	queries 383:15,17	362:16 366:3	159:20 180:20
public 4:18,22 8:19	266:3 272:11	query 316:4	374:15 379:18	196:20 217:15
18:11 34:11 77:16	284:13 303:7	Quest 71:12	380:14 386:22	248:4 251:15
117:7 134:18	313:5 345:20	question 15:1 18:8	391:9,11 394:22	272:19 299:20
187:12 194:1,9,13	353:17 373:10	18:13 19:14 21:12	questioning 83:21	336:18 351:5
226:15 252:18	394:6,9 395:14	21:15 27:16 37:9	230:22	375:15
258:11 259:3,11	puts 34:9 301:6	38:22 39:13,17	questions 7:14	quoted 229:7

R				
r 43:9,10,11 49:21	rankings 39:18,19	ratios 114:20	157:8 159:1 162:1	152:17 154:17
66:10 97:10,12,12	260:22	raw 162:15 163:9	162:16 166:3	156:7 159:5 160:3
97:15,22 150:14	rapid 168:17 337:5	reach 163:10	172:20 175:16	166:3 167:12
209:15,21 219:18	rare 131:12	reaching 210:11	183:3 260:14	170:2 173:21
221:19 289:18	rate 4:5,6,8 13:21	reacting 379:9	313:18	174:19 176:12
290:14,19 297:13	14:5 23:3 25:20	reaction 349:22	readmitted 123:1	177:3 181:1 182:5
324:1 329:3	42:6,11,12 45:6	read 20:19 128:15	125:1 129:10	186:15 187:9
355:11	58:22 67:4 79:6	251:20 351:4	171:10 175:2	189:3 196:16
race 10:19 20:13	90:4 92:18,21	370:20	reads 374:17	197:9,18 201:5
92:17 126:8,10	93:2,5,14 96:22	reading 4:9 200:13	ready 70:16 76:7	205:18 208:16
201:3 260:13	122:7,16 125:22	201:6 202:2 210:5	77:10 82:8 84:5	211:17,22 219:2
racial 126:11	132:1,7 136:4	210:8 211:4	196:9	219:12 223:6,22
radically 45:10	139:7 143:14	212:18,20 213:1	real 18:5 76:5,5	224:4 226:3,15
296:13,19 366:10	144:22 145:4,7,17	213:17 215:1,11	98:10 176:15,18	232:7 240:14,16
367:9	145:18 146:10,10	217:3 218:22	189:17 203:15	242:4 246:4,4,6
radiologist 374:17	146:12 147:4,22	219:9 221:8 223:7	242:17 257:18	248:9,14 249:7,14
radiology 374:14	148:6 162:15	223:8 228:1 230:4	333:22 367:14	252:18 253:14,22
raise 161:21 395:22	163:3,5,8,9 172:9	readmission 4:8	375:21 381:1	256:21 267:16
raised 44:11 52:21	176:16,19 186:4,8	6:1 13:4 122:7,14	391:11	269:1 271:22
80:21 390:2 396:1	292:7 332:13	122:16 123:12	realities 154:12	279:12 282:17
raising 7:15 201:14	333:8 370:13	124:20 125:22	155:10 289:13	283:13 284:5
Raj 2:6 200:14	rated 26:2,22 71:19	126:3,20 129:18	reality 150:11	287:22 292:1
228:12	91:17 94:2,3 95:1	131:2,8 132:5	329:20 335:11	296:15 299:13
Ramon 1:18 49:20	95:2,3 118:21,22	135:13 136:2,4,21	realize 189:6 254:9	302:18 303:8,10
50:14 66:8 150:13	119:1,21,22	137:2,20 138:1,9	325:20	305:6 306:17
209:14 219:17	rates 27:1 45:5	139:7 141:1,7	realized 263:6	309:21 314:17
241:22 297:11	126:3,20 132:5	143:14 144:8	really 5:5 6:6 11:4	317:9 318:13
323:22 329:2	136:21 138:1,9	146:21 147:18,22	15:1 19:11 21:15	325:1 329:6 330:7
355:10	147:2 177:20	148:6 149:14,20	24:20 28:18 29:5	330:16 331:1,2
Ramon's 242:3	184:10 188:20	151:17 152:7	29:19,21 30:8	337:12 344:16,22
random 14:10	261:10 262:2	157:17 158:1,9,18	37:11 50:16 51:6	345:1 350:12,13
132:2 134:11	311:14 312:3,5	161:5,9,17 165:10	51:7 66:18 69:6	350:19 354:18
randomized 370:21	rate's 58:22	167:4,7,11,12	71:21 74:10 76:12	356:4 358:6 369:9
371:3	ratification 396:19	168:13,18 171:3,8	76:14 77:20 78:1	369:13 370:1,5
randomly 137:15	rating 95:13	172:5,9 175:14	78:9,19 83:10	376:5 379:1
314:4	156:19 368:20	176:16 183:4	87:5 88:17 89:4	381:11,13,20
range 40:22 43:8	ratings 40:4 95:10	184:10 186:4,7	94:20 102:2,16	386:7,16 391:1
51:1 61:12 77:3	97:3	190:10 232:18,22	107:6,13 110:15	393:12 394:13
108:2,5	ratio 27:21 65:19	245:14 246:13	111:2 113:7 116:2	395:9
ranging 27:2 126:3	94:8 114:10	274:20 313:8,21	121:18 124:18	reason 19:19 38:4
rank 39:16 309:18	rationale 10:6	314:6,10	125:3 131:7,13	53:11 58:14 130:5
310:11	32:20 159:22	readmissions	132:3 135:3,8,8	139:21 167:19
ranked 27:19 28:13	185:17 191:16	115:18,22 116:2	136:17 138:4,8,12	183:12 215:13
71:1	197:15 200:19	122:18 123:4	138:19 140:12	244:6 272:2 277:6
ranking 186:21	201:1 225:21	130:11,20 132:4,8	142:22 143:14	286:13 303:11
187:10,21 188:5	233:8 244:14	133:14 146:2	144:9 148:11	331:1 361:13
	rationalize 242:14	151:3,15 155:16	149:13 150:4,21	reasonable 64:10

106:15,16 221:21 225:21 241:3 244:13,18 245:18 385:17 reasons 129:11 131:9 132:17 185:4 220:19,21 221:1 253:1 266:3 267:7,11 268:9 273:12 286:19 320:9,10,19 344:11 345:14 reassure 257:5 recall 40:22 recalling 229:5 recap 4:2 5:12 receive 202:11 210:20 222:8,9,15 251:6 318:18 385:14 received 119:7 218:11 235:2 249:17 receiving 49:19 216:20 235:21 322:9 recognition 158:22 159:3 255:3 recognized 295:21 recognizing 172:14 172:19 recollection 61:9 recommend 118:5 270:7,18 272:5 273:7,9 290:12 396:15 recommendation 31:15 272:10 283:6 301:13 302:11 361:22 362:2 recommendations 77:7 274:19 297:2 361:18 recommended 270:2 reconciled 300:9	reconciliation 141:13 144:9 168:16 reconsider 333:7 reconsideration 307:4 reconvene 264:10 record 82:15 88:8 88:13,16,20,22 89:20 96:7,10 119:20 120:7 161:12 164:5,10 164:15,18 176:8 181:1 192:8 238:7 252:19 258:11 259:16 264:13 335:15 398:11 records 23:6 181:11 186:9 336:3 recovery 242:6 reduce 151:16 155:21 177:20 186:4 347:7 redundant 340:8 reevaluation 50:3 66:15 refer 128:11 241:8 reference 34:5 referred 11:18 44:19 referring 53:13 77:6 182:3 189:7 359:8 362:1 refers 278:6 refined 30:5 365:20 reflect 116:13 234:18 268:2 376:22 reflected 116:16 reflection 44:3 81:5 reflective 152:11 reflects 80:9 308:3 reformulate 55:10 refute 323:21 regard 151:5 170:11 235:14	251:6 322:6 regarding 72:7 94:19 173:20 306:21 307:1 341:20 regardless 146:3 regards 323:10 340:18 341:19 342:9,11 369:12 region 27:4 391:1,4 regional 47:14 register 281:2,9 registry 40:12 80:8 261:7 regression 91:6 regressions 30:1 regular 377:16 rehab 148:1,19 219:22 221:3 224:10 229:6,8 251:21 362:13 RehabCare 2:10 rehabilitate 220:17 rehabilitation 1:15 147:22 152:20 209:5 220:12 252:22 253:10 308:11 373:2,4,7 rehash 352:14 reinforce 158:19 reiterate 177:15 rejects 62:10 relate 195:11 296:10 related 4:20 5:20 9:21 16:11 44:7 63:15,17 64:21 107:10 112:10 131:15,17 136:13 222:15 233:5 264:4 265:2,4,8,8 265:16 266:8 270:4,9 272:22 278:7 281:14 287:14 307:9 313:8 315:12 350:11 353:18	354:21 355:21 356:4 363:14 376:3 relates 118:9 134:7 207:5 relationship 16:4 57:5 184:20 210:22 225:16 230:14,18 232:14 241:4,9 relative 48:20 156:4 316:22 369:14 relatively 45:18 78:7 81:3 83:20 151:1 309:19 310:9 350:12 382:6 relevant 15:4 47:6 92:3 103:12 182:20 214:5,14 333:10 359:15 365:8 reliability 11:19 14:14 27:13,14,19 28:1,5 39:14 93:22 94:2,6,12 127:10,11,15 137:9,10 184:19 185:1 197:5,20 198:2 199:6 218:16 reliable 309:5 365:6 reliably 89:12 relies 258:4 reluctant 51:9 rely 135:3 remain 16:18 173:14 186:20 remaining 31:7 87:12 176:2 237:3 237:10,13 remains 42:4 remarks 100:4 remember 47:11 70:15 100:21	135:12 170:14 176:6 180:1 278:13 323:8 remembered 79:21 remind 120:7 191:3 259:5 265:3 266:10 327:21 344:21 reminder 199:21 200:12 remove 333:15 358:10 removing 330:12 renal 99:13 renaming 358:15 render 33:15 repeats 376:18,18 repercussions 180:19 repetitively 169:14 reply 212:4 317:17 report 65:12 71:6,7 97:18 102:14 128:11,15 130:20 159:17 224:17 275:5 334:10 345:17 365:12 395:15 reported 20:5 77:15 172:6 199:19 216:13 263:4 276:3 367:5 369:21 reporting 6:14 8:19 9:5 117:7 134:19 187:12 194:10,13 226:15 260:18,21 294:7 311:14 339:21 367:17,18 Reports 6:13 represent 59:8 99:8 126:4 194:21 representative 217:1 representing 24:13 193:2 259:18 represents 104:15
---	--	--	--	---

request 32:1 35:1	181:9 197:7 289:1	resumed 192:8	right 18:11 20:2	343:16 344:10
requesting 17:19	291:5 322:4	264:13	21:14,19 22:6	353:3 355:3,9
require 8:9 41:17	335:19 363:17	resuscitate 55:3,5	33:21 35:12 36:6	356:10 360:20
133:17 181:8	372:3 396:4	resuscitated 55:22	38:8 46:15 53:20	362:20 363:18
198:2 221:22	responded 393:9	56:6	65:11 66:16 67:8	369:4 376:16
233:11 240:22	responding 31:6	retracted 57:14	74:21 77:12 83:22	377:11 379:17
276:8 278:14	69:17 71:22	Reuters 261:18	89:22 95:17,18	381:8 387:8,20
365:11	196:16	revealed 280:2	96:3 102:11	388:8 392:6,22
required 120:2	response 23:22	reverse 130:9	104:11 107:8	397:16
197:12	27:16 28:17 62:18	343:21	108:4 109:5	rightfully 176:1
requirement 21:2	67:16,17,22 68:18	review 95:15 106:7	112:11 114:9,14	rigor 260:5 393:21
226:9 228:19	83:14 102:2	128:14,16 133:18	116:3,14,19	rigorous 263:9
381:18	119:11 140:10	136:22 170:13	132:12,13,21	394:10
requirements	159:21 165:4	244:4 264:3	133:14 135:1,20	rise 257:21
240:3	167:15 168:17	282:16 341:2	135:22 137:12	risen 247:20,20
requiring 125:9	173:19 175:19	351:4 359:14	138:20 143:18,20	Risha 1:22 31:1
230:4 244:2,5	304:21 311:7	366:8 367:1,2	144:19 146:21	36:14 37:9 52:5
rereading 324:10	351:3 357:16	397:17	147:1,9,21 148:5	54:11 60:17 66:9
research 1:15 3:3,4	359:5 369:6	reviewed 6:7	148:8,8 151:4,6	66:19 71:16 79:12
3:6,10,14,15,23	376:10 388:4	359:22	152:18 153:7,21	81:15 83:8 84:1
24:14 84:9 232:1	393:4	reviews 69:15	154:9,10 155:13	114:1 121:4 122:9
323:13 373:10	responses 62:20	251:21	161:20 174:12	159:14 162:5
378:1	396:9	revisions 365:12	177:11 181:14	163:15 180:7
researcher 84:8	responsibility	revisit 371:21	183:7 187:10	182:10 188:5
researchers 193:5	153:13 243:18	revisiting 331:16	189:5 190:7,13	190:1,21 256:3
residents 70:1	responsible 218:8	re-estimated 43:1	200:6 202:12	279:16 300:2,3
resolve 271:8	341:11 386:4,6,13	re-hospitalization	203:3,19 205:8,13	309:10 311:5
resolved 202:21	Responsiveness	144:22 145:7,14	206:2,11,17	381:6,8
301:10	390:12	145:18 146:10,12	208:16 209:4,7,8	Risha's 175:20
resource 211:8,18	rest 288:15	147:2,4 188:20	210:15,17 212:13	risk 4:3,5,7 5:21
221:13	restart 125:12	re-implementation	214:16 215:1,13	7:9 8:1,6,11 9:10
resources 159:8	restricted 194:3	50:8	216:4 218:9	9:15,16,17,22
181:3 380:20	288:4	re-vascularization	221:10 225:12	10:12,14,15 11:3
respect 93:12 94:1	restricting 109:14	337:5	227:20 228:3	11:11 15:4,6,8,9
118:19 119:18	result 21:12,13	re-vote 396:10	232:21 236:18	15:19,21 16:2
125:19 126:10,12	134:10 135:7	Rich 34:15	238:18,20 243:22	17:5 19:3,15,16
126:21 128:17	220:13 256:10	RICHMOND 2:3	244:20 245:1	20:14,20 21:4,17
129:5 153:18	258:16 349:3	23:1 24:8 25:15	247:11 254:13,14	22:1,11 25:21
185:14 235:13	350:2	26:8,20 27:15	269:3 283:3 290:7	28:20 29:19 30:17
242:19 306:12	resulted 383:20	28:12 70:22 82:13	290:14,17 295:17	30:21 31:21 32:2
respectfully 382:1	results 16:17 21:11	82:22 151:8 223:4	297:6 298:7	32:13,22 33:16
respects 204:10	58:3 61:7 62:8	231:3 249:21	301:21 313:1	34:10,22 36:18
respiratory 55:6	88:6,11 89:1	250:5 279:11	318:6 320:11	37:5 38:10,12,16
110:1	96:12 134:16	280:7 298:15	321:13 323:5,14	38:18 41:10,19,20
respond 95:16	197:6 198:8 256:9	rid 11:2 298:1	328:19 329:1,2	43:1,5 46:19,21
111:11 116:7	277:12,19 316:22	317:19,21 342:16	334:1,22 336:5	53:2,19 57:8,9
128:10 162:7	332:8 342:2	343:7,12	337:18 339:11	59:18,20,21 60:1

62:13,17 66:21 81:19 85:2,9,11 86:11,14 87:9 88:3 90:10 91:4,5 94:7 96:7 99:2,6 99:15 100:7 101:9 104:8 105:15 107:11,13 108:11 108:12,21 115:4,7 116:9 117:15 121:15 122:6,16 125:9 126:19 128:14 138:18 140:14,18 141:4,7 144:7 149:14,19 152:4,5,6,11 155:22 170:15,22 171:12,13 172:5 172:21 175:10,11 191:18 196:22 199:7,10,12,14 228:21 291:21 292:18 300:13 302:8 306:14 307:18 308:5,9 309:18,20 310:9 310:11 311:17,20 312:4,8 313:12 314:11 382:2,5 risks 152:8,13 risk-adjust 99:9 113:1 175:10 risk-adjusted 10:5 10:8 25:1 27:1 247:4 382:4 risk-adjusting 113:21 risk-for 30:7 risk-standardized 84:13 85:4 93:5 96:22 risk-stratified 23:4 RN 2:17 3:22 road 95:11 240:14 248:6 252:20 Rob 3:17 192:21 196:5 200:7 222:3	229:16 240:1 robustness 348:21 349:14 ROC 106:13,14 role 104:5 139:15 170:3 373:14 roles 65:6 rolling 268:13 rolls 269:4,4 Romano 3:18 24:6 24:9,10 25:13 32:5 33:5,6,21 39:7 40:6 43:11 43:17 46:18 47:11 51:19 52:3,11 54:13 59:10,16 63:4,7 72:18,21 76:8,10 80:3 292:10,10,14 295:10 305:7,7,10 307:16 308:1 309:2 room 1:10 35:17 160:15 172:13 282:7 291:8 304:19 316:9 326:9,13 roughly 210:18 round 374:9 378:4 route 49:19 routinely 46:18 120:3 row 356:18 RSMR 4:6 rubber 95:11 176:15 rule 19:21 rules 366:9,16 ruling 251:8 run 21:9,22 62:9 65:6 261:6 389:5 running 148:22 rural 18:16 rural/urban 19:4 rushed 351:5 r-squared 43:13 97:11,15	S	Sacramento 24:12 sadly 89:11 safe 222:17 safer 172:22 safety 79:6 168:19 374:5 Salina 2:11 49:1 72:5 173:17 178:10 241:17 255:9 285:11 301:9 385:11 sample 30:17,18 Sanders 2:5 Sarah 3:19 259:13 satisfaction 28:5 satisfied 78:1 83:3 save 129:1 252:10 saw 12:12 28:16 50:4 101:18 194:1 223:8 233:3 276:11 355:15 380:17 saying 21:1,13 48:2 56:3 75:5,10 101:18 102:3 104:18 145:11 154:2,20 159:21 167:12 210:6 213:4,6,8 215:8 228:18 233:8 240:2 242:1 243:13 244:1,12 245:5 247:18 257:7 267:13 286:21 290:1,11 304:12 311:19 312:1 323:2 329:11 331:20,22 332:7 337:15 343:14 347:11,17 348:5 349:13 358:3,11 389:21 390:4 says 20:21 67:3 153:22 154:13 156:13 174:5	201:19 205:6 214:1 215:10 249:1 scale 6:14 39:22 40:14,20 89:10 96:2 99:21 195:18 198:5 205:8,11 262:13 386:19 scales 195:20 196:1 198:6 scan 388:18 390:15 SCARIANO 2:5 156:10 322:14 326:19 scenario 288:1 schedule 377:15 scheduled 130:16 schedule's 7:1 School 2:4,9 24:12 science 151:16 382:12 scientific 27:13 93:22 117:8 275:6 scientifically 263:8 scope 218:9 219:5 score 14:5 96:2 198:7 201:6,9 262:13 371:6,12 371:13 scored 195:5,17 201:5 210:2 scores 39:22 95:2 191:2 198:15 199:1 scoring 235:1 238:8 screen 67:17 356:18 scroll 67:16 search 243:20 second 13:7 99:18 123:5,18 129:7 136:10 171:6 223:13 241:14 269:20 292:3 313:4 318:8 321:1 321:6,15 322:1	secondary 67:18,20 317:13 337:8 Secondly 17:4 Secretary 390:12 section 69:10 73:19 203:11 223:5 227:1 230:19 302:20 312:15 sections 48:4 237:14 secure 172:22 see 8:2 9:18 10:6 14:7 19:16 20:16 22:2 23:22 33:4 36:6 37:2 39:7 67:5,16 72:1 75:9 87:13 93:5,13 96:16 97:17,18 98:10,16 100:2 101:7 103:9,15 105:6,22 131:20 132:6 133:6 144:3 145:15 153:14 156:13 157:8 160:2,7,15 164:9 164:22 169:20 170:5 180:4 183:22 195:5 199:2 202:17 207:5,6,7,16 208:13 210:10 219:2 223:6,12 224:7 230:6,12 231:19 232:13,17 242:5 245:16 248:2 249:3 250:10 251:17 264:1 268:22 270:1 273:4 279:9 281:6 285:1,2 294:3 296:9,17 297:1,14 299:3 300:9,20,21 303:21 308:6,6 312:21 316:16 317:7 325:10 331:4 351:8 352:5
--	--	----------	---	---	---

359:14 367:10,15 368:13 369:13 370:6 378:11 383:18 387:5,7,22 390:20 396:8,22 seeing 46:4,17 82:18 138:6 153:16 173:12 224:1 231:6,12 234:1 249:16 275:11 325:16 337:21 seeking 389:21 seen 40:18 86:9 142:16 156:17 195:4 231:9 235:20 253:17 366:5 390:2 sees 343:17 segmented 153:7 seizing 80:14 172:18 seizure 294:13 select 314:4 selection 265:14 self 125:2 send 78:4 116:15 255:13 274:15 327:4 395:16 397:16 sending 153:3 171:17,19 337:11 396:21 senior 2:13,15,17 5:15 111:3 sense 44:3 56:8 72:20 100:7 133:19 219:14 224:11 242:20 270:19,20 348:6 375:14 sensitivities 260:12 sensitivity 20:12 29:10 sent 200:9 244:22 separate 45:4 55:2 69:8 76:14 137:9	140:13 179:11 195:9 214:10 246:9 294:4 302:21 311:15,17 312:7,8,9 331:11 338:9 339:20 359:2 separated 337:4 separately 45:12 59:18 60:10 80:5 312:11 sepsis 366:17 September 396:14 septic 131:16 366:15 series 64:14 152:12 serious 133:19 217:16 365:18 seriously 246:17 serve 42:13 332:11 361:5 service 115:17 222:10 230:18 232:15 391:3 services 158:17 200:21 202:12 208:20 210:20 216:21 221:5 222:8 226:1 229:11 230:15 235:21,22 240:6 241:4,4,11 243:8 244:14,15 247:17 253:21 255:13 362:13 SES 92:17 93:4,6 126:8,13 session 363:19 390:3 398:7 set 8:12 21:5,9,21 22:1,4,4 39:18,19 40:11 42:21 43:2 45:20 76:7 86:7 94:9 118:2 137:17 184:17 193:14 212:21 213:9 239:11 283:15	298:5 307:3 311:21 312:9 315:2 326:17 334:5 354:12 357:20 360:7 362:10 375:18 378:10 388:15,17 sets 25:8,9,10 72:22 339:1 366:7 397:4 setting 117:9 153:1 184:1 277:10 284:11 306:16 314:1 323:15 344:16 354:4 360:13 settings 142:19 230:6 247:2 302:10 setting-specific 303:4 settled 119:2 setup 387:11 seven 83:17 127:7 190:18 236:6 Seventeen 124:8 seven-level 198:6 seven-page 27:16 28:17 seven-plus 23:22 seven-point 195:18 severe 109:8 211:17 308:3 severely 101:5 175:6 severity 30:7,9 33:12 36:8 39:2,6 42:14 77:19 80:10 98:17 99:21 110:6 110:10 111:6 121:14 161:7,16 162:2 173:21 174:1,13,14,16,19 191:18 217:13 260:10 262:11,18 263:7 368:20 369:14 shades 56:14	Shahian 261:5 shape 375:20 share 159:18 224:11 shared 370:11 SharePoints 192:17 sheet 318:8 353:5,6 Sheth 2:6 192:15 200:16 303:14 shine 177:13 shining 173:9 shocking 45:7 372:16 Shore-LIJ 1:25 short 119:11 124:2 124:3 127:17 264:9 shortly 73:1 84:18 short-term 262:10 262:17 shot 220:8 373:2 show 59:2 92:17 132:20 168:4 189:1 197:14,21 198:1 233:19 261:1 308:16 375:18 381:19 showed 42:2 94:6 showing 28:2 93:7 94:7 104:1,4 125:21 126:11 162:2 183:1 184:9 203:12 229:8 243:3 322:21 shown 40:4 168:6 223:18 231:12 327:5 shows 67:10 219:20 222:13 224:8 shrinkage 11:18 sick 46:14 48:11 79:9 101:5 sicker 82:3 170:19 175:9 side 72:2 82:2 111:19 255:3	300:11,11 sides 288:8 346:14 sight 222:1 sign 34:21 280:10 341:10 355:3 signal 43:21 44:1,1 137:13 142:16 189:14 signal-noise 137:9 signal-to-noise 27:21 significance 78:11 significant 46:21 51:20 58:10 103:4 105:9 161:16 176:17 180:6 217:21 228:19 249:17 255:18 307:19 379:11 significantly 187:14 263:16 silliness 337:2 siloed 153:7 similar 25:3 36:3 50:4 122:4 152:4 161:5 177:21 235:12,13 251:5 271:7 272:20 277:5,19 287:12 293:1 318:15 352:13 355:4 378:10 similarities 13:17 91:9 234:21 similarly 137:12 277:20 293:9 simple 134:8 153:5 166:7 205:5 358:9 387:5 simplest 215:12 simply 54:3 187:12 278:19 311:13 312:4 sincere 150:16 single 20:6 153:22 195:8 singly 320:1
---	---	---	---	---

singular 257:1	smooth 173:2	347:9 348:17	speaks 269:2	195:15 200:20
sit 133:11 349:10	smoothed 13:21	355:2 357:7	276:10	207:22 208:15,19
369:8 384:13	smoothing 11:17	385:10	special 295:6	209:7,17 216:15
sitting 49:4 251:19	14:15	sort 36:11 81:8	344:11	219:19 220:3
situation 153:6	SNF 385:9	95:8,10,12 98:7	specialists 54:22	229:10 231:10
154:22 225:7	soapbox 254:11	101:5 102:1 135:5	specialize 335:13	233:5 238:2
242:3 293:1	societal 211:9	166:11 167:20	specialties 189:13	239:15,18 243:7
338:12 346:6	societies 13:2	168:21 177:12	specialty 189:4	255:2 258:5 375:7
situations 57:4	128:13 239:9	187:15 219:15	259:17	382:21
154:14	society 259:18	220:11 221:3	specific 8:8 10:11	speech-language
six 70:19 82:19	socioeconomic	225:7 237:5 254:9	12:8 76:20 77:7,8	3:17 193:13
185:11 198:21	10:20 260:13	255:6 257:19	117:22 145:4,10	194:22 195:10
sixteen 125:15	software 79:5	268:16 269:10	146:18 147:7	207:12 210:4
234:5	310:22	277:10 288:7	203:16 204:18	216:20 223:15
size 27:6	sole 50:1	316:13 325:8	209:6 211:1 219:6	224:19 230:5
sizes 309:5,13	solicit 35:4 377:6	326:8 331:4	219:9 227:11,21	232:3 235:21
skilled 146:7	377:10	349:20 368:13	238:2 247:14	239:2 241:10
skimmed 203:10	solidify 179:5	374:10 383:13	260:1 274:18	244:8,15 369:7
slide 7:20 9:8 10:8	somebody 14:21	384:8 390:17	279:18 306:13,16	Speech-Languag...
11:8 12:14 13:5	74:2 115:5 124:6	393:3	322:2 343:2	193:1
14:6,17 16:7	129:11 216:8	sound 12:18 221:20	specifically 13:2	speed 237:11
20:19 65:2 198:14	246:8 316:12	263:8	30:13 34:2,16	374:16
272:21 273:16,17	321:7	sounding 238:6	39:8 95:7 215:10	spend 85:19 325:1
274:16 276:20	somebody's 47:7	sounds 119:5	368:14	spent 45:16,17 83:5
279:6	something's 279:10	129:13 174:15	specification 27:18	85:17 100:18
slides 108:10	somewhat 101:11	190:11 248:18	96:1 278:12	145:12 159:11
264:20 269:22	153:20 181:1	325:16 345:5	specifications 9:4	295:6
slight 61:10 360:22	251:7 274:4 309:1	363:18	17:4 265:20	split 288:14,16,17
slightly 138:17	364:1	source 171:7	270:11 273:4,13	301:18 350:3
144:1 161:12	soon 317:11	284:12 306:8	278:7,10,15 282:3	splitting 204:11
311:18 314:13	sophisticated 382:6	307:13 335:5,14	335:4	292:2
362:20 372:4	sorry 31:12 33:6	336:3	specificity 29:11	spoke 172:11 176:7
slips 112:5	58:7 60:18 68:10	sources 276:7	specifics 205:14	Spoken 4:13,14
SLP 196:2	73:17 76:8 84:2	278:13 329:20	211:2,19	sponsored 193:8
SM 3:5	84:10 85:22,22	335:13	specified 117:21	spot 149:13
small 11:20 45:18	125:16 135:21	space 390:21	128:5 197:18	squads 386:8,9
78:7 224:22 303:2	143:21 144:14	spark 138:4 186:15	198:16,17 199:13	squared 43:10
320:21 324:13	147:14 149:7,10	speak 35:16,17	199:18 336:7	97:13
333:4 371:19	167:13 169:4	69:12 83:2 117:5	342:1	squishiness 330:15
372:17	174:11 188:1	129:2 138:10,11	specify 18:22	stabilize 11:16
smaller 213:1	215:6 231:19	169:9 252:13	288:19	stabilized 13:21
224:22 225:2,5,5	256:11 273:15,16	277:12 291:9	specifying 199:4	staff 2:13 24:16
309:4	280:14 284:3	302:1 313:1 325:6	specs 196:20 271:5	76:11 148:2
smart 296:8	292:12 295:8	336:11	353:8,10	203:22 375:9
smattering 193:19	296:6 300:2 319:6	speaking 35:8	spectrum 295:17	395:14
Smith 262:20	319:12 328:22	134:12 159:16	spec'd 351:21	stages 14:17
smoke 177:5	340:15 342:12	213:19 351:15	speech 4:15 192:11	stake 259:20

stakeholders 158:20 309:8	175:12	180:6	strategy 9:15 120:4 199:10	122:8,14,19 125:22 129:15
stamp 51:10	stat 388:17	statisticians 81:11	stratification 9:17	131:3 140:3 145:2
stand 100:14	state 25:8,9 42:20	84:16	15:19,22 16:3,5	145:8,18 146:1,16
105:16 253:20	47:13 80:13 154:8	statistics 30:16	38:10 304:17	147:8 148:11
301:20	154:8 160:22	45:8 61:16 79:14	309:4 311:1	156:20 157:1,13
standard 29:9	252:18 269:2	80:6 94:6 107:6	stratifications 46:4	161:7,16 162:1,2
39:20 40:4 42:19	367:2 386:7 388:2	130:6 139:13	stratified 45:9	188:22 191:18
75:8 95:9,15	stated 7:12 341:6	142:4 184:16	293:22 294:6,6	195:1 200:20
108:4 175:13	statement 158:5	263:4 382:3,12	296:4 311:9,14,16	204:16 205:2
227:7 247:21	160:8 165:2	status 10:20 27:6	312:7 332:13	206:21,22 210:4,7
257:14,21 326:1	203:15 226:21	32:3 33:10 37:11	333:8	212:7,19 213:2,2
standardization	341:20	47:19 52:8 60:3	stratifiers 310:16	213:6,11 214:1,4
256:7,14,20	statements 178:12	90:17 124:19	stratify 20:15,17	214:21 215:11
standardize 209:11	235:12,13 239:12	150:1 190:5	59:18 308:21	216:19 219:8
221:4 224:12,13	states 52:13 71:5	232:19 240:17	309:14 310:19	220:2 238:9
258:10	128:14 193:19	260:13	311:10 312:3,4	244:11 248:12
standardized 4:6,8	206:20 309:13	stay 41:13 44:8	334:4 337:21	255:11 259:21
94:8 114:14,15	384:19 387:12	98:7,19 99:8	stratifying 310:15	260:10,10,14
122:7 126:20	statin 385:15	138:13 190:9	Street 1:10	262:10,11,13,18
209:4,10 253:5	stating 119:1	333:17 350:3	strengths 12:6	263:1,7 284:18
standardizing	167:19	stayed 201:9	271:16	285:7,13,14 288:3
256:17	statistic 40:21 41:1	steering 1:4,9	stretch 151:13	288:5,17,18
standards 230:4	42:3 43:3 45:11	14:20 15:2 16:19	strictly 211:13	290:22 291:1,17
381:21 396:17	60:10,20 61:3,10	17:18,22 18:1	strikes 348:19,20	292:7 295:4,4
Stanford 1:22	62:2,17 78:9	263:20 280:13	349:2 389:10	299:17,18,21
stars 367:14	88:15 106:13,14	281:18 397:19	stringent 78:12	306:12 307:19
start 8:15 10:1 15:7	106:17,21 107:18	stems 115:14	stroke 1:15 4:5,6,8	317:8,12 322:8,17
16:8,10 22:22	134:7,9 136:11,18	163:17	6:13,14 23:2,10	324:2,2 327:4,15
24:2 84:4 89:22	138:11,22 139:1,9	step 14:9 139:17	25:22 29:8,13	330:17 331:1
95:6 108:14	143:17 159:19	205:17 224:12	33:19 39:22 40:13	332:13 337:3
117:14,16 149:3	160:3 161:13	255:5 333:9 390:1	40:20 41:17 42:14	354:4,7,17,17
175:14 208:10,21	162:11,20 163:18	394:5,9	45:1,9,12 50:2,5	355:7 356:6 359:3
220:21 239:1	164:10,19 166:12	stepping 228:12	50:10,17,17 58:11	364:7 365:9 368:4
240:8 258:21	166:20 167:5,16	steps 4:23 14:12	58:12,14 59:12,19	368:6,13,19
286:16 287:1	169:14 170:12	240:21 255:1	59:22 60:9,11	369:14 371:9
320:17 353:11	175:21 178:6	269:22 395:5,13	61:4 63:10,13,15	373:17,19 384:19
359:11 365:3	180:10,11 184:12	398:4	64:21 65:6,7,9,10	384:20 386:19
372:11 391:3	184:18,19 185:1	steward 23:3	65:14,21 71:7	387:19 388:16,20
396:13	254:3 263:3	stewardship 271:9	73:5 75:3 77:18	389:1,5 390:3
started 12:10 24:7	statistical 8:8,11	sticking 241:21	80:10 81:3,9	397:6
40:8 112:16 192:6	9:16 11:10 12:8	stimulate 194:18	84:17 85:7 89:8	strokes 25:19 44:22
264:16 373:5	12:17,21 13:2	stimulating 225:9	89:10 90:5,9,22	45:6 46:11 58:16
starting 123:16	14:16 15:12,13	stop 17:13 18:2	92:20,21 93:1	58:16,18,19 80:5
144:3 287:4 338:6	16:17 29:18	199:20 350:14	96:2 99:20 101:2	81:6 109:7 209:17
389:20 396:20	128:13,19 260:6	strata 171:12	106:2 109:19	213:16 294:1,19
starts 148:17 174:8	statistically 51:20	198:22 199:1	110:1 121:14	304:10 306:14,15
	59:2 103:4 105:9	311:17 312:9		

306:16 309:12 323:4 stroke-specific 368:17 strong 89:19 173:14 262:7 330:12 382:12,17 strongest 262:9 362:5 strongly 36:9 222:14 260:17 291:19 structure 26:12 232:16 250:7 structured 376:5 structures 230:15 structure-process 224:8 struggle 105:12 135:8 189:16 240:7 254:15 struggled 218:4 221:2 232:8 249:8 struggling 215:21 245:22 studied 149:12 studies 134:2 138:7 144:4 204:22 219:4,7 229:7 239:3 study 105:19 133:13 167:12 170:4 180:17 181:2 226:22 238:9 365:16 stuff 202:17 215:14 373:11 378:7 386:10 391:20,20 397:7 stumbled 69:5 subacute 147:21 subarachnoid 299:19 subcategories 74:5 subject 211:7 262:19 submission 22:15	202:16,17 245:10 252:4 submit 22:9 112:4 136:13 225:20 233:9 366:22,22 367:1 377:17 submits 111:15 submitted 122:12 194:11 196:13 233:21 245:19 347:15 348:3 367:7 395:21 submitting 347:19 348:1 subsequently 263:10 subset 16:21 17:2 212:18 235:20 substance 29:6 substantial 41:2 121:8 substantiated 81:4 subtypes 45:1 288:20 299:21 subtype-specific 299:14 successful 381:1 sufficient 87:11 181:6 228:14 233:7 243:11 309:14 suggest 176:4 180:13 185:8 225:6 250:15 299:10 330:11 339:17 341:9 346:18 350:22 367:2 368:18 377:7 381:17 382:1 suggested 319:9 372:11 394:1 suggesting 40:18 59:11 64:10 132:4 133:5 142:3 176:1 330:13 suggestion 32:14	114:17 312:6 317:2 319:20 333:7 340:4 348:11 352:4 358:14 372:4 381:22 383:1 suggestions 17:17 364:19,21 375:6 377:8 381:3,14 383:15 suggests 101:14 131:1 suitability 121:3,21 191:10,12 suitable 329:12 SUKO 2:7 56:17 69:11,21 111:12 112:11 177:21 245:13 346:12 347:16 348:12 SULLIVAN 2:8 200:1 201:16 202:5 212:15 224:10 233:13 234:15,20 235:7 236:11 249:6 369:5 382:20 summarize 191:2 summarized 24:21 375:1 summary 6:6 177:6 233:10 374:11,18 summer 397:21 398:2 superior 266:1,2 267:10 271:18 272:3,6,12,13,15 273:1 275:9 276:1 276:10 282:7,12 282:17 285:11 290:10 328:12 331:3 superiority 275:1 279:4 331:12 support 141:14 150:4 160:7 199:12 296:3	340:1 341:7 361:21 370:4 supported 12:19 291:18 supporting 121:15 197:15 362:6 supports 10:7 240:5 262:7 341:13 suppose 186:6 290:17 336:12 supposed 179:5 203:17 326:6 353:3 384:14 386:15 387:12 supposedly 229:8 sure 7:2 12:12 24:8 30:22 33:9 44:21 47:2 50:16 52:22 56:10 68:1 69:7 78:10 89:2 98:13 112:22 116:22 119:5 122:3 133:2 133:7 140:12 145:21 146:3 153:1 160:3 177:9 203:2 235:8 240:11 246:18 254:22 255:16 268:3 283:2 319:13 321:16,22 335:8 348:8 359:20 361:11 362:17 363:3,4 366:3 369:11 382:17 384:4 385:14 386:17 397:3,6 surgery 48:8 217:20 261:6 354:21 355:1 surprised 373:1 384:2 surprising 162:4 surprisingly 71:2 survey 396:22 survival 113:19	survive 308:8 Susannah 3:2 84:7 291:7,11 susceptible 293:17 293:19 suspect 104:9 107:9 157:18 Suzanne 2:19 6:9 63:2 264:19 395:4 swallow 292:4 swallowing 4:12 252:1 swaths 392:1 sway 75:21 swelling 129:20 sympathetic 248:4 symptom-specific 39:4 synch 304:3 syndrome 295:18 system 1:17,25 3:3 3:6,10,14,15 30:3 30:4,11 34:10 110:2,7,20 111:5 148:2 153:6 179:9 193:8,10,17 194:4 216:14,17 222:13 235:16 347:13 372:1,9 384:19,20 389:2 391:15 392:3 systematic 251:20 367:4 381:11 systemic 390:17 systems 3:9 25:11 47:13 71:5,7 109:11 138:12 150:18 173:1 179:12 267:21 269:9 340:4,8 systolic 293:10
T				
table 102:14 103:6 159:10,16 160:11 223:17,18 254:12 298:4 322:7				

337:18 338:3 364:8 375:1 382:16 tabled 302:22 take 21:4 35:8 39:8 58:18 78:20 84:1 86:15 87:6 96:5 98:22 122:3 129:20 130:8 135:7 137:14 140:2 146:6 148:9 153:11 162:15 170:7 192:4 213:20 215:16 216:2 220:8,14 243:15 254:12 258:15 264:8 282:14 289:21 292:17 302:12 308:4 323:1 324:3 326:8 327:12 373:11 taken 39:17 78:5 109:8 115:6,10 182:7 295:11 333:5 338:5 350:19 takes 151:4 378:12 talk 11:9 12:15 28:22 86:16 98:9 129:6 221:12 225:15,17 241:17 267:18 269:15,16 299:7 327:20 351:3,10 363:21 373:19 talked 20:11 38:11 65:1 107:2 159:6 166:18 228:20 229:15 235:19 236:13 248:15,15 250:2 253:9,11 264:20 322:19 354:3 356:6 388:12 393:21 talking 37:9,10 53:22 54:1 55:4	84:13 85:18 109:4 111:9 118:10 138:17 147:11 148:11 159:12 162:10 168:15 177:17 181:11 213:17 246:15 247:22 253:14 266:11 267:17 273:21 290:7 295:7 297:9 325:9 332:20 349:9 373:21 talks 256:22 target 17:6 265:10 265:12 266:20,21 270:14 273:3 289:8 297:21 task 19:7 86:18 87:8 89:13 99:5 134:3 182:8 TBI 378:15 387:15 teaching 27:5 169:20 170:2 181:13 team 24:18,18 33:18 65:5 109:15 169:8 193:3,5 283:18 348:8 395:7 tease 155:17 157:6 technical 97:18 130:20 278:14 292:4 technically 273:8 teleconference 3:24 telephone 18:9 28:13 259:7 395:1 tell 6:9 21:21 56:7 136:7 183:20 284:19 322:22 327:11,12 328:10 336:13 339:7,9 350:17 389:7 395:5 telling 206:3 320:1 320:2	tells 136:4 183:21 370:22 ten 58:21 70:18 127:19 191:7 tend 62:13 tended 187:11 tendency 371:16 Tennova 2:6 tens 104:15 tense 345:6 term 78:12 346:1 358:3 terminology 55:13 terms 9:9 15:12,18 19:15,22 26:13,20 27:18 29:4,13,21 31:16,20 37:4 41:21 42:16,19 49:11 53:17 62:18 63:22 71:4 75:9 75:19,21 81:18 91:16 92:14 93:4 102:20 104:17 108:10 116:18 117:19 123:19 159:6,7 197:11,13 197:19 204:11 205:1 206:3 207:4 210:13 211:19,20 211:22 223:10 224:22 225:4 226:13 235:1 238:21 245:22 249:13 255:18 265:19 266:7 269:4,9 287:2 300:11,17 304:6 310:8 312:18 318:3 319:15,17 335:16 337:18 339:3 360:16 374:16 377:4 379:9,17 385:13 Terry 298:14 Terry's 279:9 tertiary 263:17 368:5	test 46:18 60:9 62:7 62:9 167:18 307:17 346:21 347:6 348:2 testable 132:12 tested 29:15 41:6,7 42:1,19 48:17 351:21 testing 40:16,22 48:8 52:14 197:5 198:4,5,8 308:11 348:8 376:18 tests 78:11 Texas 64:18 thank 5:4 6:15 7:4 18:3 24:1 25:12 32:9 35:22 36:15 80:2 89:21 120:20 122:2,11 147:13 149:9 150:12 151:6 173:16 188:12 196:3,4 200:16 237:16 251:14 255:8 257:3 259:1 263:20,21 299:21 312:12 325:12 326:16 340:14 360:16 362:9 365:22 367:21 375:3 381:12 382:18 383:21 395:3,8 398:5,6 thanks 157:15 169:3,6 259:14 347:16 361:12 372:22 381:9 398:8,9 THEBERGE 2:19 6:11 26:5,18 27:10 28:9 70:18 82:9,19 83:17 91:21 92:11 93:19 94:14 118:15 119:14 120:22 121:22 124:3,8 125:15 127:7,19	185:10 190:18 191:7 192:1 228:8 234:5 236:6 250:21 395:6 theoretical 95:14 theoretically 39:16 44:16 73:9 272:16 therapies 158:11 therapist 224:11 369:8 therapists 220:3 therapy 209:17 315:3,4,10,11 317:14 328:3 333:21 358:18 thereof 63:21 Therese 2:3 22:22 25:14 70:13,21 76:7 151:7 222:20 223:3 228:4 231:2 241:22 249:19 thing 5:9 8:5 9:2 13:12 40:7 42:18 45:14 49:14 56:12 67:11 83:10 95:12 97:5 100:10 106:4 107:3 137:8,9,21 150:6,14 162:14 167:18 171:5,6 177:12,17 178:18 184:7 190:1 203:9 203:15 205:5 206:19 214:20 215:8 221:21 223:13 239:21 252:18 258:8 267:14 277:11 291:2 296:15 299:16 305:3,19 316:17 319:19 333:7,10 339:17 344:8,21 346:12 346:18 347:18 356:16,21 363:9 374:19 377:19 378:8 386:2 391:14 392:8
--	--	---	---	--

things 7:17 15:3,7 16:1 17:7 28:18 32:10 39:9,10 48:6,9,21 51:16 66:1 70:3,3,5,10 71:19 74:6 98:18 99:19 103:17 105:3 107:14 110:20 116:9 117:17 130:7 131:21 132:2 136:20 138:4 139:20 140:4 142:21 147:19 149:4,12 154:9 155:21 157:11 161:18 165:22 168:14,21 170:16 171:1 172:4,17,18 173:6 176:5 178:13,13,15 179:4 181:12,16 182:2 184:4,15 189:12,19 194:8 197:6,8 202:15 211:16 214:13 215:18 217:15 219:14 221:14 224:15 227:4 232:21 244:9 267:4 270:1 277:15 281:16 288:11 289:10 294:18 295:2 300:20 304:6 319:11 320:3 333:18 338:9 339:19 342:15 349:8 351:14 352:17 364:6,13 365:11 369:11 376:8 377:5,6 379:3 387:5,13,15 389:8 394:16	28:6 29:20 30:3 36:21 37:21 38:14 38:15 39:1 40:3,3 45:7,10,13 47:6 47:10 48:12 49:5 50:6,13,15,21 51:6,15 56:4,8,12 56:19 57:6,13 59:10 60:19 62:22 63:20 73:1,13 74:13 76:12,18 77:14 78:4,20 80:9,21 81:16,22 82:1,4 84:12 89:4 98:20 99:18 101:17 103:5,20 105:12 111:12,19 112:7 113:5,13 116:2 120:17 121:17 125:12 132:2,8,10,12,14 132:19 133:1 136:17 138:1,10 142:10,13 143:7 143:22 146:19,22 147:21 148:10,19 149:3,11,13,18 150:1 151:12,14 151:19 153:9,11 153:13 154:6 155:5 156:4 157:5 158:5,22 159:2,5 161:18 162:12,22 163:7,16 164:2,18 165:1,18,21 166:2 166:8,9 167:14,18 168:8,14 170:12 172:5 174:3 175:20,22 176:3 176:13,16 177:22 178:8 180:10,20 181:4,12,15 182:5 182:17,20 186:11 187:10 188:16 189:6,8 192:4 194:7,12 197:14 197:16 198:12	200:16 203:8 205:6,13 206:15 207:1 208:1,16 209:12 210:7 212:10,15 214:19 215:8 216:6,18 219:16 220:10,15 220:19 221:6 222:16 225:3,12 225:14 226:3,8 227:8 228:17 230:17,21 231:4,6 231:20 232:4 233:13 234:20 235:9,11 236:11 237:1,19 239:16 239:22 240:1,15 241:6,22 242:17 242:22 247:22 248:2,3,6,15 249:8,12 250:6 251:15,16 252:3,5 252:8,20 253:1 254:7 255:10,13 257:6,7,12,17,20 258:2,7,9 267:7 267:11,17 268:2 269:2,7,8 272:2 272:12,13,14,18 273:8,14,15,16,20 275:1,3,5,16 276:19 278:1,11 279:9,13 280:7 282:20 283:15,22 284:2 285:3,10,22 286:4 287:15,19 288:7 289:13 291:16,22 292:3 294:22 295:7,11 297:11 300:5 302:13,14 303:13 303:16 304:5 305:3 306:6,22 307:6 309:11,16 310:8 311:13 314:16 316:12 317:6,17,18 318:1	319:20 322:14,16 323:5,6,9,20 325:13 326:14,16 326:20 327:15 329:6,9,10,15,18 330:5,13,14,18 332:1,3,4 333:5 333:13,14 334:8 334:12 335:17 336:6 337:13,13 337:17 338:4,6 341:5 345:5,9,19 350:9,12,19,22 351:2 352:8,12 353:4 355:12,16 356:5,7 357:17 358:2 359:1 360:12,13,15 363:20 364:12 365:2,17 366:4,11 366:11 367:8 370:10,15 371:16 371:21 372:5,15 372:19,20 375:2,5 375:8,13 376:3,4 376:6 377:21 378:9,11 380:3,4 380:6,11,13 381:6 381:10 382:10,13 382:22 383:1,10 383:19 384:6 385:19 388:6,7 390:18 392:8,10 392:15,16,18 393:3,6,19 394:8	Thompson 261:18 thoracic 261:6 thorough 381:11 thought 7:6 10:20 13:15 28:6 32:20 152:16 169:15 201:14 233:22 271:21 321:5 326:10 328:22 341:15 362:4 394:1 thoughtful 180:21 181:15 thoughts 71:14 83:16 175:19 340:20 thousand 103:14 217:8 thousands 229:7 threats 28:20 three 8:2 23:12 25:17 28:18 45:1 82:9 83:2 91:15 91:16 93:14 94:14 95:2 109:17 118:15 124:9 172:6 195:7 235:2 235:8 250:21 260:1,18 262:8 269:22 288:21 299:17 321:12 358:19 threshold 184:17 380:8 383:9 threw 325:8 thromboembolism 357:1,10 throw 168:22 249:3 315:19 throwing 74:20 177:4 thrown 147:3 thumbs-upped 272:17 THURSDAY 1:6 TIA 328:7,17 330:2 330:4,12,13,16
--	---	--	--	--

331:4,18,20	43:12 44:10 62:21	248:20 249:5,19	toss 340:5	transparency
332:13,16 333:7	65:18 67:3,6	250:13 251:1,14	total 108:16 216:19	76:13
333:10,15 336:22	73:22 83:22 91:18	252:9,12,15 255:8	261:21	transparent 32:17
337:4,20 340:19	92:1,6,12 93:15	256:2 257:3	totally 65:22 133:7	trash 74:21
341:6,8,14 345:16	93:21 94:11,16	258:14 259:1,9	176:19,20 289:3	trauma 132:15
TIAs 318:3	95:5,21 96:18	263:21 264:7,15	297:21 339:21	treat 38:6 48:11
tied 140:5 214:7	97:2,7,10,14,21	266:18 268:8	359:9 363:1	295:1
321:9 335:5	98:2 100:9 101:12	279:22 280:5,9	tough 182:8	treated 101:20
till 174:7	101:21 102:8	281:10 283:21	trace 151:3	210:4,8 212:8,11
time 11:7 35:9	106:22 108:6,22	287:16 288:22	traditionally 187:9	212:13,22 213:10
47:19 83:6 85:17	112:6,12 113:10	292:12 299:8	187:18	213:12,14 217:3
85:19 87:15 90:21	114:1,11 116:6	307:8,20 315:18	train 291:8	219:4 221:8 224:2
98:1,22 99:4	118:11,17 119:4	317:16 321:21	trained 373:6	231:7
100:18 104:22	119:16 120:10,13	325:19 330:10	training 224:20	treatment 158:12
105:14 119:13	120:20 121:2,7,17	332:22 336:22	transfer 23:13	158:14 193:14
133:12 137:11,12	122:2 123:16,21	339:16 354:15	29:16 44:8 46:19	195:1,11,16
137:13,14 143:5	124:4,10 125:11	360:18 368:1	48:12 51:16 58:13	197:15,16 201:21
145:13 146:18	125:17 127:3,9,14	370:11 372:2	58:17 60:3 72:7	202:2 208:3,7,18
159:12 171:3,4	127:21 129:3	375:4	72:11,12 81:1,17	222:15,19,21
173:22 174:7,8,17	134:5 136:9	title 374:20	81:18 82:3 102:5	225:17 230:18
174:19 175:7,11	139:16 140:10	Toby 200:7	164:6 260:11	231:8 233:5 238:1
175:12 178:20	141:19 142:11,17	today 6:16,18,21	305:16 313:17	239:3,11 241:7
196:12,21 207:16	143:9 144:12,15	8:3 9:18 54:4	323:14	242:15,17 244:10
223:21 224:4,7	144:19 146:17	84:12 215:18	transferred 47:17	258:8
233:16,21 236:15	147:6,12,15 149:6	219:15 263:4	49:17 59:13 72:10	treatments 196:2
237:12 246:21	150:12 151:7,22	264:22 266:17	81:7 86:1,13	225:22 230:5
249:15 250:16	156:8 157:14	272:18 279:16	90:14 123:2,6	238:3 242:8
257:16 259:4,7	159:13 161:3,15	332:5,7 333:2	306:2,3 307:14	tremendous 177:2
264:6 284:11	162:5,9 163:15	357:21 363:21	308:8,9,12 313:19	368:8
295:7 303:1	165:4 166:14	364:1 376:4	387:9 388:21	tremendously
304:12 318:18	167:20 169:5,11	told 6:7 62:16 84:2	transferring 46:14	368:4 386:6
325:1 349:12	173:16 174:2,10	197:8 284:9 344:7	47:8 77:22	triage 252:13
351:5 357:21	174:18 175:17	374:15 380:4	transfers 29:17	trial 55:17 221:20
364:4 365:7,8	177:14 178:10	TOLIN 2:9 330:21	46:5,8 47:5 48:15	370:21
376:16 377:2,18	179:13,19 180:7	Tonn 3:19 259:13	49:13 51:14 58:9	trials 358:2,5,8
380:20 381:6,20	182:9,18 183:5	259:13	59:9,14 85:20	tried 55:1,1 98:18
385:18 388:17,20	185:6,12 186:19	tool 71:12 87:4	305:4,5,14 306:21	143:4 232:7 284:4
394:16,18,21	187:4,20 188:4,13	179:10 209:2,3	307:2 308:16	299:4 303:4
395:1,8,19 396:6	189:22 190:11,16	257:1,13 258:4	transfer-out 48:18	377:14 380:3
Timeline 4:23	190:20 191:5,9,20	tools 178:16,19	transient 294:12	390:15
times 137:7 157:12	192:3 206:18	179:8,10 258:6	337:2	trigger 56:1 124:22
277:17 366:13	229:4 234:13,17	top 6:10 326:11	transition 232:19	trouble 286:2
time-stamped	236:3,9,18 237:16	topic 248:18	transitional 168:20	troubled 350:8
391:17,18	239:6 241:13,16	364:12	transitions 138:2	troubles 350:1
tiny 266:14	242:21 244:17,21	Topics 4:19	158:12 260:15	troubling 224:16
Tirschwell 1:11,14	245:2,11 246:2,14	topped 315:21,22	translate 110:15	true 37:12,16 76:2
6:4,15 38:21 43:9	246:19 247:8	318:19	378:2	112:8 132:11

143:16 165:2,16 173:5,6 326:1 355:7 387:14 truly 143:6 213:15 truth 134:12 375:11 try 110:10 133:4 140:13 143:18 150:16 155:17 165:9,19 166:6 170:9 177:20 179:5 184:4 188:16 192:5 196:9 210:21 241:12 264:9 271:17 281:6 297:15 351:14,22 353:20 359:15 377:9,11 trying 7:17 11:2 18:18 20:3 86:20 87:3 129:14 131:20 135:14 138:4 163:11,13 168:4 174:21,22 179:22 184:5 187:7 215:3,21 224:12 240:21 242:22 251:20 257:20 258:12 274:6 279:18 286:17 295:16,16 298:1 321:16 334:11 349:10 351:12 353:19 378:1 380:21 382:11 386:3,17 392:22 tumor 294:14 turn 33:1 169:21 169:22 367:11 377:10 395:4 turned 37:15 turning 37:18 Turnpike 388:20 turns 131:13 162:1 215:22 294:12	twelve 127:19 185:10 Twenty 93:19 twenty-five 217:7 Twenty-one 26:18 91:21 Twenty-two 92:11 two 14:11,20 16:22 27:19 28:14 39:12 65:22 70:18 74:18 82:10,14,20 84:12 93:19 94:2 95:2 97:1 98:20 116:8 119:21 121:5 123:19 124:1,3 125:16 127:1,12 128:6 143:21 154:15 171:19 176:14 191:2,12 195:7 208:15 223:4 235:4 236:7 267:7 271:11 274:3,4 275:17 277:17,17 278:6 284:3 289:18 293:4 300:11 304:8,13 305:3,11 312:2,6 313:7 315:3,7,8,9,11,16 316:6,8 317:9,19 318:3,9,14 319:14 321:14 322:15 323:1 325:21 327:7,9 328:13 329:4,7 331:10,22 336:16 338:9 339:20 345:1 351:13 354:13 355:5,5 357:7 358:8 360:8 371:3 375:4 twofold 209:13 two-day 320:8 two-stage 351:18 tying 170:15 type 18:22 27:5 45:9,12 58:14	59:12,15 60:11 61:4 81:3,9 214:7 305:13 316:16 types 58:11 60:9 62:6 179:12 239:4 288:3 378:22 typically 9:15 10:19 19:2 105:11 111:16 195:5 210:5 typing 110:14 t-PA 6:12,12 387:18 <hr/> U UB-40 307:11 UC 24:11,19 33:18 65:6 UHC 261:17 ultimate 306:4 339:4 ultimately 155:7 158:4,7 341:10 UMass 1:21 unaffected 42:3 unanimously 83:1 uncertainty 87:14 unclear 67:22 312:14 uncomfortable 165:16 349:6 uncommon 109:17 undergo 209:17,18 undergoes 209:22 underneath 296:13 understand 7:17 33:14 48:2 52:8 67:1 68:11 86:20 100:14 102:2,19 107:16 112:17,22 114:20 115:11 135:14 136:1 141:10 152:10 154:3 162:11 174:22 186:16 214:18 224:18 228:12 238:18	241:12 245:5 246:8 249:22 254:21 258:10 297:22 338:21 339:3 346:7 understandable 77:16 understanding 18:19 75:6 111:7 117:5 158:13 159:7 227:3 298:19 354:6 understood 145:21 212:16 undiagnosed 294:13 undisciplined 337:10 undocumented 150:5 unfair 355:13,16 unfairly 33:3 50:9 unfolds 148:14,16 Unfortunately 178:15 289:11 uninsured 65:9 unintended 380:2 unit 385:9 United 128:14 193:18 206:20 309:13 university 1:14,16 1:18,19,22 2:4,9 3:18,22 66:4,6 71:11 261:17 unknown 90:17 unnecessary 320:22 unplanned 131:8 146:2 unravel 153:4 unrelated 122:18 131:15 unreliable 90:18 135:1 unresolved 198:10 unsympathetic	155:14 untested 275:8,10 275:12 upcoming 377:13 update 35:5 updated 28:16 206:19 361:16,18 379:19 updates 375:16,18 upstream 380:21 uptake 256:8 urban 18:16 urge 360:19 URL 280:15 usability 69:6,9 71:1,4 73:14,19 82:8 118:18,20 119:9,11 147:11 164:2 185:13,15 190:17 226:7,13 260:4 275:22 379:19 use 9:1 12:17 21:16 25:8,10 27:20 29:22 30:3 31:19 40:14 47:13 51:16 52:1 63:19 64:7,8 66:2,5 68:8 69:10 69:12 75:4 99:15 99:22 103:8 109:15 110:8 111:5 115:12 120:6 129:14 136:17 139:3,3 156:16 162:18 178:21 179:8,10 189:16,20 193:6 194:2,3,5 195:6,7 195:21 198:6 199:5 211:8,18 218:13 232:1 238:7 256:22 258:6 260:17,19 260:20 263:10 276:3,4,5 278:4 281:4 322:6 338:13,14 341:7
--	--	---	--	---

341:14 342:16 358:3 361:16,18 379:21,22 380:9 383:4 useful 62:12 74:7 166:13 186:13 usefulness 89:9 379:21 useless 135:16 user 64:14 135:4 294:3 username 280:20 users 73:4 uses 68:16,20 82:16 85:15 88:8 usual 234:10 308:1 usually 109:8 322:10 327:13 UTI 366:15 utilization 179:3 221:13 U.S 25:20	118:14 119:2 127:22 128:1,4,6 128:7 151:20 164:3 185:9 197:5 197:22 198:1,4,4 205:15 218:17 248:12 260:4 271:21,22 272:1 300:19,22 346:15 347:6 valuable 240:6 310:10 332:8,16 value 101:1 182:14 185:15,19 188:8 247:19 248:17 254:20 257:9,19 277:1,2,3 278:1 279:5 291:17 304:8,13 312:21 363:2 370:15 371:22 values 66:22 67:7 72:2 80:16 value-based 115:15 VAN 2:10 144:21 146:5,22 147:9,14 188:15 207:21 220:9 228:17 229:16 231:20 238:5,20 239:14 239:20 252:17 258:1 343:11 344:2 392:7 vanishingly 320:21 variability 170:5 261:9 368:8 variable 86:12 88:1 88:4 175:15 262:19 334:1,2 379:4 386:6 variables 15:10 16:1 19:16 42:2 56:20 57:1 67:15 68:12,13,15 87:18 91:3 96:5 98:7 99:7 100:2 102:22 103:15 104:1,12	164:8,13,14 165:20 179:16,17 180:2 182:6 262:15 300:12,16 314:12 variably 162:2 variation 27:1 42:13 43:14 44:7 52:18 53:12,17 87:12 111:20 126:2 170:10 variations 27:3 28:2 varies 154:8 variety 8:1 12:2 118:6 257:1 304:11 various 46:3 310:20 377:17 387:12 vascular 109:10 vast 45:2 309:12 340:7 vastly 142:4 vector 67:14 vegetative 80:13 vendor 261:1,10,20 vendors 261:11,12 261:16,17 venous 357:1 verbiage 249:1 versa 344:9 version 68:15,20,21 284:16 versus 18:16 19:3 43:5 59:19,22 115:9 131:15 242:7 266:8,22 267:20 275:18 276:8 277:1 278:12,16 287:21 290:9 293:3 310:3 310:5 323:18 327:21 338:14 341:22 355:20 356:19 358:20 360:8 365:13	371:7 vice 2:13 150:7 344:9 view 264:22 331:1 violation 41:14 237:6 viral 293:12 Virginia 2:7 virtually 310:17 virtue 224:6 visit 201:7 visits 371:9 volume 48:22 57:6 voluntary 367:17 367:17 volunteer 386:8 vote 26:4,17 27:9 28:8 70:16 76:7 82:8,8,18 83:16 91:20,20 92:10 93:18 118:13 124:12 127:6,17 127:17 182:10 185:22 231:18 234:4 243:14 250:15 255:15 271:21 343:7,8 394:5,9 396:14 voted 25:17 91:16 93:14 121:6,6 127:1,2,12 128:5 128:7 155:8 191:12 229:1 284:20 321:8 votes 235:4 voting 92:9 93:17 94:13 118:14 119:10 120:21 121:20 123:20,20 124:1,16 125:12 127:5,16 185:8 190:17 191:6,22 228:6,7 232:5 236:5 250:19 312:14 376:6 396:12 VTE 353:1,3,15	354:3,12,12 358:2 358:3,5,12 vulnerable 151:18
W				
WADDY 2:11 18:12 19:10 49:2 72:6,19 139:11,20 173:18 174:4,12 178:11 255:10 285:12,17 301:11 302:13 305:2 306:19 318:1,6,10 323:7 352:1 378:20 380:6 385:12 391:21 393:6 wait 129:21 340:16 waiting 336:18 377:4 walk 135:19 285:1 walks 101:1 walls 186:18 want 7:18,19 10:6 15:8 19:16 20:7 35:8 38:11 52:22 53:9 56:10 59:5 65:13 69:3,7 74:8 75:17 76:2,10 86:15 87:6 110:4 111:2,11 112:20 112:21 129:22 130:2 133:10,21 134:22 136:9 138:15 141:16,16 145:20 153:19 154:11 157:19 160:14 163:9 165:11 166:16 168:8,15 169:1 170:13,18 175:9 175:13 180:8 183:7 190:22 192:18 205:21 207:16 210:10 212:3 214:15 217:10,22 220:8				

223:15 225:3,15	wasted 237:12	website 34:20 79:2	111:9,12 112:18	339:2,4 356:11
226:17 237:20	WATT 3:20 316:18	79:10 279:20	116:14 117:19	366:4 369:17
240:11,14 241:11	319:4,13 325:7	weeds 60:15	124:5,7 132:3,5	373:21 376:13
248:7,19 249:6	326:14 335:22	weeks 129:12 130:1	135:12,13 138:4	378:11 381:2,5
252:10,15,18	336:10 354:9	148:14 172:12	140:15,15,17,18	382:17 385:6
254:22 265:17	355:2 357:6,13	395:9,15	140:21 141:2	388:15 390:20
268:3 269:7 274:1	way 37:19 42:16	weigh 271:16	145:1 147:1	395:4,17 396:13
274:10,15 275:2	51:7 59:5 70:15	286:21 380:10	148:10,20,21,22	397:4,8,14,15,17
277:6 278:10	74:2 77:4,19	weighing 371:11	149:1 151:2	we've 7:22 22:15
280:16 286:20	78:12,12 96:3	weighted 27:22	153:21 154:2,20	40:8 41:22 49:3
287:1,8 292:6	101:4 110:13	43:4 370:16	155:1,9 156:5	69:5,16,22 70:4
300:4 304:14	113:13 124:12	Weill 2:1	162:10,13 163:4	88:5,9 100:17
308:4 316:15	130:10 132:3	welcome 4:2 6:5	163:11,13 168:4	107:2 121:18
322:3 333:6	137:10 138:18	381:3	173:12 175:20	133:3 137:6
335:19 344:20	143:18 146:13	went 24:5 79:2	177:17 178:8	147:16,18 155:8
348:15 358:14	147:11,20 153:6	130:13 192:8	181:11 187:6	159:11 168:3,15
363:3,4,16 365:13	154:6 155:11,17	194:1 201:9	192:4,12,14 203:4	172:4,7 196:8
370:4 371:4	156:5 157:5	238:11 264:13	203:18 204:13	203:2 207:6
381:10 382:21	166:22 169:18	375:7 398:11	206:4 210:16	248:14 275:1
385:18 393:17	170:5 172:13	weren't 102:22	213:17 215:8,16	278:21 304:6
395:7 397:6	177:12 187:8,11	103:4 181:4	215:20 219:14	313:2 318:19
wanted 24:5,6	187:18 189:10	196:20 318:2	223:18 224:1	331:13 337:16
56:17 63:7 69:11	201:4,8 207:19	384:9	226:22 227:1,2	350:18 360:10
73:12,18 74:18	210:12,22 211:12	West 2:6	228:6,13 231:6	363:19 366:5
89:5 108:8 109:2	211:20 215:12	we'll 16:6 24:2	232:12 240:10	376:12 377:13
117:11 159:9	216:10 224:13	61:19 69:15 122:4	243:2,3 247:12,20	380:3 389:13
162:6 185:2	225:4 237:11,15	192:5,16 205:14	247:22 248:1,3,18	395:10
191:16 196:6	237:22 246:12	232:17 250:17	252:3 253:14	whatsoever 214:7
198:10 254:2	251:11 268:19	274:15 280:12	255:7,14 256:16	white 12:21 56:12
312:22 313:3	270:16,22 286:8	298:8 329:18	257:9,14 264:7,15	whites 93:1
340:19 352:1	289:16 298:1	348:16 350:3	264:22 266:11,12	Whoa 70:22
364:4 395:12	309:21 315:15	356:11 391:6	270:7 273:20	wide 77:2 261:10
wants 34:22 46:13	324:20 326:7	395:15 396:5,7,21	276:22 278:4	widely 35:10 51:1
168:10 252:5	343:18 369:2	we're 5:8,9,10,14	279:15 283:16,19	widest 276:3 289:7
305:1 312:19	371:11 376:4,8	6:19 11:1 13:9	285:8 286:21	WILLIAM 1:16
355:19	385:6	19:13 20:2 21:13	290:1,7 295:15,16	willing 294:1,5
warrant 295:5	ways 122:5 137:5	22:21 27:10 48:3	297:18 298:20	296:2 309:6
warrants 180:21	166:10 297:3	50:9 52:13 53:21	303:17 305:22	wind 320:8,14
wars 156:12	310:20 314:14	54:1 56:21,21	306:1 309:6	winding 387:14
washed 59:3	331:3 350:22	60:14 62:5 64:1	312:20 316:20	window 174:8
Washington 1:10	352:12 389:9	65:8,14 68:8,14	317:3 318:4,9	365:7,8
1:14	weakness 375:10	68:22 69:4 71:1	325:9 326:6,17	winds 294:20
washout 308:15	weaknesses 12:6	74:20 78:19 82:12	330:5 331:10,11	winging 349:20
wasn't 36:16,16	271:16 375:21	84:11,12 89:11,16	331:14,15,20,21	wish 382:8
58:9 230:7 239:17	web 9:6 166:4	89:17 96:14 97:6	331:22 333:2,18	women 93:2
276:20 333:1	181:16	99:1 100:22	333:19 334:21	wonder 38:9 81:19
waste 133:21	WEBER 2:21	103:22 108:12,20	335:1,11 338:6	229:5 256:10,18

122 4:8
13 283:21 284:1
13th 395:17 397:15
136 27:2
14 10:15 23:14
 126:1 193:7,11
15 193:5 194:9
 388:21
15th 1:10
15,000 202:11
 203:13 210:19
 216:11
150,000 216:21
 217:2
1525 358:20,20
16 193:6 194:9
 217:2
16.5 200:19 212:21
17 25:20 28:9
18 6:7 23:11 71:4
 275:18 288:14
 299:1,3 301:18,19
 302:15
18-plus 301:21
19 26:5 27:10 126:4
192 4:9
1955 6:14

2

2 26:6 27:10 172:12
 223:17,17 242:2,2
 275:10 317:12
 322:8 324:2,12,14
 324:18 380:9
 396:21 397:1
2a 27:14
2b.5 178:8
2,000 215:22
2,494 206:17
2.5 261:13
20 240:21
20-minute 264:9
2008 25:22 50:4
 74:8
2009 262:21
2010 261:8 263:19
2012 1:6

2017 6:13
2022 6:12
2026 4:5 84:2 260:3
 306:20
2027 4:7 122:6,12
 260:4
21 1:6 124:5 388:18
22 4:5
234 4:10
24 198:21 199:7
 365:9
25 200:21 207:8
25th 126:5
25,000 259:18
260 4:18
264 4:20
273 4:21
28 261:21,22

3

3 129:12,21 130:1
 324:15,18 358:18
 385:18
3M 3:8 32:12 34:8
 79:5 261:18
 276:12 279:18,20
3rd 397:20
3,000 193:17
3-year 261:15
3:11 398:11
30 25:22 90:8
 102:14 115:4
 123:9 172:16
 206:21 314:8
30-day 4:5,7 16:21
 42:21 43:5,15,18
 44:15 84:13 85:5
 90:3 122:6 126:19
 174:8 260:2
 263:11,14 274:9
 286:2,11,20
 287:13,21 288:1,4
 289:10 291:21
 298:20 305:19
 310:5 396:1
30-days 304:11
300,000 193:12

36 159:17
364 4:21
394 4:22
395 4:23

4

4 28:10 63:19 64:11
 73:21 193:22
 194:4 242:15
 245:20 324:15
 353:4 366:13
4th 397:20
40 43:14

5

5 6:8 64:10 254:4
 284:2 290:8 317:8
 324:2 352:16,21
 380:9
5-plus 242:16
50 371:12
500 193:18

6

6 4:2 385:18
600 172:11
65 90:6 122:15
 275:19 288:5,15
 298:22 299:3
 301:19 302:8
 308:21 309:14,15
 310:2,19 311:21
65-plus 301:22

7

7 4:3
70-plus 64:19
73 27:2
75 207:9 214:1
75th 126:5

8

8 105:13
8:00 1:10
8:06 5:2
80 221:7 327:12
83 261:14
84 4:6

85 368:22

9

9 102:14 120:9
9th 1:9
90 326:2 370:13
 371:7,8,17
911 388:18
92 371:7,12
99 327:16

C E R T I F I C A T E

This is to certify that the foregoing transcript


In the matter of: Neurology Endorsement
Steering Committee

Before: NQF

Date: 06-21-12

Place: Washington, DC

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